UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

LEE MEMORIAL HEALTH SYSTEM, d/b/a LEE HEALTH, *Plaintiff*, v. Actavis LLC, Actavis Pharma, Inc. F/K/A Watson Pharma, Inc., Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc., Allergan Finance, LLC F/K/A Actavis, Inc., Amerisourcebergen Corporation, AmerisourceBergen Drug Corporation, ANDA, Inc., BHC Service Company Henry Schein, Inc., Cardinal Health, Inc., Cephalon, Inc., CVS Healthcare Corp., CVS Pharmacy, Inc., Discount Drug Mart, Inc., Endo Health Solutions, Inc., Endo International PLC, Endo Pharmaceuticals, Inc., Henry Schein Medical Systems, Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., Janssen Pharmaceuticals, Inc., Johnson & Johnson, Mckesson Corporation, Miami-Luken, Inc., Noramco, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc., Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc., Par Pharmaceutical, Inc., SPECGX LLC, Teva Pharmaceutical Industries, LTD, Teva Pharmaceuticals USA, Inc., Walgreen Eastern Co., Inc., Walgreens Boots Alliance, Inc. A/K/A Walgreen Co., Wal-Mart Stores East, LP, Wal-Mart, Inc., Watson Laboratories, Inc., *Defendants*.	**MDL 2804** **)** **) Case No. 1:17-MD-2804** **)** **) Judge Dan Aaron Polster**

COMPLAINT FOR

DAMAGES AND DEMAND FOR JURY TRIAL

Plaintiff, Lee Memorial Health System, d/b/a/ Lee Health (hereafter alternatively, "Plaintiff" or "Lee") by and through its undersigned counsel, hereby brings this Complaint for Damages and Demand for Jury Trial against Defendants, and in support thereof, alleges as follows:

INTRODUCTION

1. Plaintiff brings this civil action to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance caused thereby, and to recoup the monies that have been spent, or will be spent because of Defendants' false, deceptive, and unfair marketing and/or unlawful diversion of prescription opioids (hereinafter "opioids") – a dangerous, highly addictive, and often lethal class of narcotics comprised of natural, synthetic, and semi-synthetic painkillers.[1]

2. Defendants manufacture, market, and sell prescription opioids, including branded medications (e.g.) OxyContin, Opana, Subsys, Fentora, and Duragesic, as well as generics labeled as oxycodone, methadone, and fentanyl. Historically, because they were considered too addictive and debilitating for the treatment of chronic pain (e.g., back pain, migraine, and arthritis),[2] opioids were used only to treat short-term acute pain or for palliative (end-of-life) care.

3. However, by the late 1990s, and continuing through today, each Defendant began a comprehensive marketing scheme designed to persuade a wide swath of previously-untapped health care providers, including hospitals, and patients that opioids can and should be used for chronic pain. By broadening their group of targeted health care providers, Defendants made it much more likely that patients would become addicted and suffer other adverse effects from the long-term use of

[1] As used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.
[2] In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

opioids. In connection with this scheme, each Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioid use while overstating the benefits of using them for chronic pain.

4. Defendants' efforts were and continue to be wildly successful. Opioids are now the most commonly prescribed class of drugs, generating $11 billion in revenue for drug companies in 2014 alone and resulting in a national health crisis of opioid addiction. In 2014, more than 47,000 people died in the United States from lethal drug overdoses. In 2015, that number exceeded 52,000,[3] a number representing far more deaths than car crashes and gun homicides combined. In 2016, the number of drug-related deaths grew to more than 64,000. In all, more than 183,000 people died in the United States between 1999 and 2015 from overdoses directly related to prescription opioids,[4] and current estimates suggest 145 people now die every day in the United States from opioid overdoses.[5]

---

[3] Rose A. Rudd, *et al.*, *Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010-2015*, 65 Morbidity & Mortality Weekly Report 1445-52 (2016), available at https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm (hereinafter "Rudd, *Increases in Drug and Opioid-Involved Overdose*").

[4] That number does not take into account the staggering number of additional illicit opioid deaths that can be related back to doctor-prescribed opioids; indeed, four out of five new heroin users began first with prescription opioid misuse. Christopher M. Jones, *Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers – United States, 2002-2004 and 2008-2010*, 132 (1-2) Drug & Alcohol Dependence 95-100 (Sept. 1, 2013), available at http://www.drugandalcoholdependence.com/article/S0376-8716(13)00019-7/pdf. Still, most misused prescription drugs are obtained directly or indirectly from a doctor's prescription; only 4% of persons misusing or addiction to prescription drugs report getting them from a drug dealer or stranger. Anna Lembke, *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, And Why It's So Hard to Stop*, 18 (John Hopkins University Press 2016); "[U]nintentional poisoning deaths from prescription opioids quadrupled between 1999 and 2010, outnumbering deaths from heroin and cocaine combined." Kathleen Frydl, *Purdue Pharma: Corporate Fraud With a Body Count*, Alternet (May 18, 2016), available at https://www.alternet.org/drugs/purdue-pharma-corporate-fraud-body-count (hereafter "Frydl, *Purdue Pharma*").

[5] Patrick Keefe, *The Family that Built an Empire of Pain*, New Yorker (Oct. 30, 2017), available at https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain (hereafter "Keefe, *Empire of Pain*").

5. In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors…[m]any of [whom] were even taught – incorrectly- that opioids are not addictive when prescribed for legitimate pain"[6]

6. Like many states across the country, Florida is suffering the effects of this unprecedented addiction epidemic. Florida healthcare providers wrote 67.1 prescriptions for opioid medications per 100 people in 2015 and 66.6 per 100 people in 2016. Of the 33,000 people who died nationwide of opioid overdoses in 2015, approximately 12% were Floridian. On May 4, 2017, Governor Rick Scott officially declared the opioid epidemic a public health emergency in Florida, stating, "The individuals struggling with drug use are sons, daughters, mothers, fathers, sisters, brothers, and friends, and each tragic case leaves loved ones searching for answers and praying for help. Families across our nation are fighting the opioid epidemic, and Florida is going to do everything possible to help our communities."[7]

7. Drug manufacturers' deceptive marketing and sale of opioids to treat chronic pain is one of the main drivers[8] of this catastrophic epidemic. Prescription opioids have historically been used for short-term, post-surgical, and trauma-related pain, and for palliative end-of-life care primarily in cancer patients. Because opioids are, by their very nature, highly addictive and dangerous, the U.S. Food and Drug Administration ("FDA") regulates them as Schedule II Controlled Substances, *i.e.*, drugs that have a high potential for abuse and that may lead to severe psychological or physical dependence.

---

[6] Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at http://turnthetiderx.org/.
[7] Michael Auslen, *Gov. Scott declares public health emergency over opioid crisis,* Miami Herald (May 3, 2017), available at http://www.miamiherald.com/news/health-care/article148355444.html.
[8] The other main driver of this epidemic is both the drug manufacturers' and wholesalers' failure to report suspicious orders as required by state and federal law, discussed *infra*.

8. That prevailing and accurate understanding of the increased risks and decreasing benefits of long-term opioid use limited drug manufacturers' ability to drive sales. In order to decrease reasonable concerns about opioids and to maximize profits, opioid manufacturers, including Non-Parties, Purdue, Insys and Mallinckrodt ("Non-Parties") and Defendants, Johnson & Johnson, Janssen, Endo, Cephalon, (individually defined in § II *infra*) (collectively, the "Manufacturing Defendants") engaged in a concerted, coordinated strategy to shift the way in which doctors and patients think about pain and, specifically, to encourage the use of opioids to treat not just the relative few who suffer from acute post-surgical pain and end-stage cancer pain, but the masses who suffer from a multitude of common chronic pain conditions.

9. The Manufacturing Defendants' (and Non-Parties') intention was to normalize aggressive prescribing of opioids for chronic pain by downplaying the very real risks of opioid usage, especially the risk of addiction, and by exaggerating the benefits of use for chronic pain. To accomplish this goal, they intentionally misled health care providers, including doctors, as well as patients about the appropriate use, risks, safety, and efficacy of prescription opioids. They did so directly through sales representatives and marketing materials and indirectly through financial relationships with academic physicians, professional societies, hospitals, the trade association for state medical boards and seemingly neutral third-party foundations. False and misleading messages about the safety, addictiveness, and efficacy were disseminated by infiltrating professional medical societies with shills, and crafting and influencing industry guidelines in order to disseminate false and deceptive pro-opioid communiqués under the guise of science and truth.

10. The Manufacturing Defendants (and Non-Parties) assured the public and prescribers that the risk of becoming addicted to prescription opioids among patients being treated for pain was less than 1%. In reality, many people with no addiction history can become addicted after just days

or weeks of use.[9] Estimates for the risk of addiction range up to 56% of patients receiving long-term prescription opioid painkillers.[10] Indeed, almost one in five people who take an opioid for only ten days will still be taking opioids one year later.[11]

11. By 2012, Florida doctors were writing 73 opioid prescriptions for every 100 Florida state residents.[12]

12. In addition to the substantial increase in use as a result of Defendants' (and Non-Parties') marketing schemes, opioid analgesics are also widely diverted and improperly used, and the widespread abuse of such has greatly contributed to the national epidemic of opioid overdose deaths, addictions. [13] The U.S. Department of Health and Human Service reports that opioid-abuse related hospitalizations in Florida statewide increased by thirty-nine percent (39%) between 2009 and 2014.[14]

13. This epidemic and its continuing consequences could have been, and should have been, prevented by Defendants who control the U.S. drug distribution industry and the Defendants (and Non-Parties) who manufacture the opioids. These Defendants (and Non-Parties) have profited greatly by allowing the geographic area served by Plaintiff to become flooded with opioids. For purposes of this Complaint, the "geographic region served by Plaintiff" means Lee County, but

---

[9] Lembke (2016), *supra* n.3, at 22.
[10] Bridget A. Martell, *et al.*, *Systemic Review: Opioid treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction*, 146(2) Ann. Intern. Med. 116-27 (2007), available at http://annals.org/aim/article/732048/systematic-review-opioid-treatment-chronic-back-pain-prevalence-efficacy-association.
[11] Sarah Frostenson, *The Risk of a Single 5-Day Opioid Prescription, in One Chart*, Vox (Mar. 18, 2017), available at http://www.vox.com/2017/3/18/14954626/one-simple-way-to-curb-opioid-overuse-prescribe-them-for-3-days-or-less.
[12] *Opioid Painkiller Prescribing Infographic*, Centers for Disease Control and Prevention: Vital Signs (July 2014), available at https://www.cdc.gov/vitalsigns/opioid-prescribing/infographic.html#map.
[13] *See*, Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, 374 N.Eng.J.Med. 1253 (2016)
[14] https://www.ahrq.gov/news/opioid-hospitalization-map.html, last viewed 2018-06-22.

typically extends beyond its borders, and includes visitors and patients from adjacent counties and outside Lee County.

14. Defendants McKesson Corporation ("McKesson"), Cardinal Health, Inc. ("Cardinal Health"), and AmerisourceBergen Corporation ("AmerisourceBergen") (collectively, the "Wholesaler Defendants") are major distributors of controlled substances that act as middlemen between drug companies and pharmacies. The Wholesaler Defendants (in addition to the Manufacturing Defendants (and Non-Parties)) were also aware of the growing epidemic from the addiction to, and abuse of, prescription opioids supplied by them. The Manufacturing Defendants (and Non-Parties) and the Wholesaler Defendants were accordingly both well aware of the quantities and frequency with which those drugs were distributed to entities in the geographic region served by Plaintiff. However, both the Manufacturing Defendants (and Non-Parties) and the Wholesaler Defendants persisted in failing to report suspicious sales as required by state and federal law. Their failure to follow the law significantly contributed to soaring addiction and overdose rates in the regional area Plaintiff serves.

15. Defendants (and Non-Parties) wholly failed to meet their obligations to timely report and put a halt to these and other suspicious sales, fueling the epidemic in the regional area served by Plaintiff.

16. The Wholesaler Defendants' violations have already led to fines elsewhere. McKesson, the largest prescription wholesaler company in the United States, agreed on January 17, 2017, to pay a $150 million fine to the federal government for such misconduct. In December 2016, Cardinal Health reached a $44 million settlement with the federal government. One month later, Cardinal Health reached a $20 million settlement with the State of West Virginia, which has been

among the states hardest hit by opioid abuse. AmerisourceBergen also recently agreed to pay West Virginia $16 million for similar violations.[15]

17. Defendants' (and Non-Parties') wrongful conduct has allowed millions of opioid formulations to be diverted from legitimate channels of distribution into the illicit black market in quantities that have fueled the opioid epidemic in the patient-demographic area of Plaintiff. This is characterized as "opioid diversion." Acting against their common law and statutory duties, Defendants have created an environment in which opioid diversion is rampant. As a result, unknowing patients and unauthorized opioid users have ready access to illicit sources of diverted opioids.

18. In their search for greater and greater profits, Defendants intentionally and negligently created conditions in which vast amounts of opioids have flowed freely from drug manufacturers to innocent patients who become addicted, to opioid abusers, and even to illicit drug dealers – with distributors regularly fulfilling suspicious orders from pharmacies and clinics, who were economically incentivized to ignore "red flags" at the point of sale before dispensing the pills.

19. If profit be the measure, Defendants' (and Non-Parties') scheme has met with tremendous success. According to *Fortune* magazine, McKesson, AmerisourceBergen, and Cardinal Health are each among the top 15 companies in the Fortune 500. The Sackler family, which owns Purdue – a privately held company – is listed on *Fortune*'s list of America's wealthiest families. "The Sackler dynasty's ruthless marketing of painkillers has generated billions of dollars – and millions of addicts."[16] However, the impact of opioid addiction has devastated the nation, emerging as one of the country's, Florida's, and Lee County's geographic region's major health threats. As

[15] Charles Ornstein, *Drug Distributors Penalized For Turning Blind Eyes in Opioid Epidemic*, National Public Radio (Jan. 27, 2017), available at http://www.npr.org/sections/health-shots/2017/01/27/511858862/drug-distributors-penalized-for-turning-blind-eye-in-opioid-epidemic.
[16] Keefe, *Empire of Pain*, *supra* n.4.

reported by *National Public Radio*, opioid addiction is thought to be among factors contributing to the United States' increase in overall rate for mortality from 2014 to 2015, the first time in a decade that the mortality rate increased. Former FDA Commissioner David A. Kessler has called the failure to recognize the dangers of painkillers "one of the greatest mistakes of modern medicine." As alleged herein, that "mistake" resulted in large part from Defendants' (and Non-Parties') intentionally false and misleading messaging, which was carefully calculated to reach as many prescribers as possible, as well as Defendants' (and Non-Parties') willingness to turn a blind eye to suspicious orders.

20. Even where some Defendants have previously been forced to admit the unlawful marketing and sale of opioids and/or the failure to report suspicious orders, the conduct has not abated because profits realized by the aggressive marketing and prescribing of opioids continue to dwarf the penalties imposed as a result of violations found.

21. For years, Defendants (and Non-Parties) and their agents have had the ability to substantially reduce the death toll and adverse economic consequences of opioid diversion, including the hospitalizations, health ruination, and death of hundreds of thousands of citizens. Substantial expenditures by Plaintiff in dealing with the problem have gone largely un-recouped and unreimbursed. All the Defendants named in this action share the responsibility for perpetuating this epidemic.

22. Each of the Defendants foreseeably caused damages to Plaintiff including the unreimbursed and/or un-recouped costs of providing (a) medical care, additional therapeutic and prescription drug purchases; (b) extensive and intensive in-hospital mandated treatment for acute and chronic health consequences of opioid use; (c) counseling and rehabilitation services; (d) security and public safety; (e) added regulatory compliance; (f) lost opportunity costs; (g) the

diversion of assets from the provision of other needed health care; and (h) increased human and resources costs as well as lost productivity of Plaintiff's employees and staff.

23. Plaintiff brings this civil action for injunctive relief, compensatory damages, statutory damages, punitive damages, and any other relief allowed by law against the Defendants who, by their actions and omission, knowingly or negligently distributed and dispensed prescription opioid drugs in a manner that foreseeably injured, and continues to injure, Plaintiff.

24. Plaintiff, Lee Health consists of four acute care hospitals: Lee Memorial Hospital, HealthPark Medical Center, Gulf Coast Medical Center and Cape Coral Hospital, and two specialty hospitals: Golisano Children's Hospital of Southwest Florida and The Rehabilitation Hospital.

25. With a total of 1812 beds, 1480 physicians on staff and over 1.5 million patient contacts each year, Lee Health is the largest public health system in the state of Florida receiving no direct tax support. Supported by more than 14,000 employees and 4,500 volunteers, Lee Health provides necessary emergency medical care and treatment for all of Lee County and the surrounding areas of Southwest Florida by offering acute care, emergency care, rehabilitative and diagnostic services, health and wellness education, community outreach and advocacy programs throughout the five county region.

26. Plaintiff, Lee Health, sits squarely in the crosshairs of the opioid-fueled-epidemic. Upon information and belief, Plaintiff spends millions of dollars each year to provide a wide range of opioid-and-addiction-related health care services for residents in and visitors to the geographic region served by it – money that it would not have had to spend but for the extreme and continuing public nuisance caused by Defendants' actions – including, as non-limiting examples, emergency room treatment for opioid overdose or other opioid abuse related injuries, in-patient cardiovascular

health care services, adult and neo-natal intensive care and critical care, and emergency response services and treatment.

PARTIES, NON-PARTIES, JURISDICTION, AND VENUE

27. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 28 U.S.C. § 1332.

28. Venue is proper pursuant to 28 U.S.C. § 1391. This Court has personal jurisdiction over each Defendant as each purposefully availed itself of the privilege of exploiting forum-based business opportunities, and the exercise of personal jurisdiction is accordingly proper.

29. Plaintiff, Lee Health, is a political subdivision of the State of Florida, i.e. Lee Health is a special district created by Special Act of the Florida Legislature to operate, control, and maintain a public hospital and other healthcare facilities in Southwest Florida pursuant to Chapter 2000-439, Laws of Florida (2000). Plaintiff is a citizen of the State of Florida for diversity purposes and has the capacity to sue and be sued.

30. Non-Party, Purdue Pharma L.P. is a Delaware limited partnership formed in 1991 with headquarters located in Stamford, Connecticut. The company maintains four operational branches: Purdue Pharma L.P., the Purdue Frederick Company, Purdue Pharmaceutical Products L.P., and Purdue Products L.P. (referred to collectively herein as "Purdue").

31. Defendant Cephalon, Inc. is a Delaware corporation with its headquarters and principal place of business located in Frazer, Pennsylvania. Cephalon, Inc. was acquired by Teva Pharmaceutical Industries Ltd. ("Teva Ltd") in October 2011. Teva Ltd. is incorporated under the laws of Israel with its principal place of business in Petah Tikva, Israel. Since Teva Ltd. acquired with Cephalon, Inc., its U.S. sales and marketing activities have been conducted by Teva Pharmaceuticals USA, Inc. ("Teva USA" and, together with Teva Ltd., "Teva"), a wholly-owned

operating subsidiary of Teva Ltd. Teva USA's headquarters and principal place of business are in North Wales, Pennsylvania. Cephalon, Inc. and Teva are collectively referred to herein as "Cephalon."

32. Defendant Endo International PLC is an Irish public limited company with its headquarters in Dublin, Ireland. Endo Pharmaceuticals Inc. (together with Endo International PLC, "Endo") is a Delaware corporation with its headquarters and principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is an indirectly wholly-owned subsidiary of Endo International PLC.

33. Defendant, Endo Health Solutions, Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

34. Defendant, Endo Pharmaceuticals Inc. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

35. Defendant Janssen Pharmaceuticals, Inc. ("Janssen") (formerly known as Ortho-McNeil-Janssen-Pharmaceuticals, Inc. and Janssen Pharmaceutical, Inc.) is headquartered in Titusville, New Jersey and Raritan, New Jersey. Janssen is a wholly-owned subsidiary of Johnson & Johnson ("J & J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

36. Defendant, Johnson and Johnson ("J & J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Defendant Janssen's profits inure to J & J's benefit. J & J controls the development, sale and marketing of Janssen's drugs. Johnson and Johnson is the only company that owns over 10% of Janssen Pharmaceuticals stock. J&J controls

the sale and development of Janssen Pharmaceuticals drugs and Janssen Pharmaceuticals profits insure to J&J's benefit.

37. J & J, Janssen Pharmaceuticals, Inc., Noramco, Inc., Ortho-McNeil-Janssen-Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc. (collectively, "Janssen") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

38. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

39. Non-Party Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona.

40. Non-Party Mallinckrodt LLC is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Upon information and belief, Non-Party Mallinckrodt Brand Pharmaceuticals, Inc., is a subsidiary or affiliate of Mallinckrodt, LLC with headquarters in St. Louis, Missouri. Upon information and belief, Mallinckrodt Enterprises, LLC is a subsidiary or affiliate of Mallinckrodt, LLC with headquarters in St. Louis, Missouri. Upon information and belief, Mallinckrodt Enterprises Holdings, Inc. is a subsidiary or affiliate of Mallinckrodt, LLC with headquarters in St. Louis, Missouri. (together with Mallinckrodt LLC, Mallinckrodt Brand Pharmaceuticals, Inc., Mallinckrodt Enterprises, LLC, and Mallinckrodt Enterprises Holdings, Inc. are referred to collectively herein as "Mallinckrodt")

41. Defendant, AmerisourceBergen is a Delaware corporation with its headquarters and principal place of business in Chesterbrook, Pennsylvania.

42. Defendant, AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. AmerisourceBergen is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Florida. AmerisourceBergen is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania.

43. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of $147 billion in 2016.

44. According to its 2016 Annual Report, AmerisourceBergen is "one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care."

45. Defendant, ANDA, INC., ("ANDA") through its various DEA registrant subsidiaries and affiliated entities, including but not limited to, ANDA Pharmaceuticals, Inc., is the fourth largest distributors of generic pharmaceuticals in the United States. ANDA is a Florida corporation with its principal place of business in Weston, Florida. In October 2016, Defendant, Teva Ltd. Acquired ANDA from Allergan PLC (i.e. Defendant, Actavis), for $500 million in cash. At all times relevant to this Complaint, ANDA distributed prescription opioids throughout the United States, including in Florida and within the communities served by Plaintiffs.

46. Defendant, Henry Schein Medical Systems, Inc. ("Henry Schein") describes its business as providing a products and services to integrated health systems, designed specifically for

and focused exclusively on, the non-acute care space. Henry Schein Inc. is incorporated in Delaware, with its principal place of business located in Melville, New York.

47. Henry Schein Inc. distributes, among other things, branded and generic pharmaceuticals to customers that include dental practitioners, dental laboratories, animal health practices and clinics, and office-based medical practitioners, ambulatory surgery centers, and other institutions.

48. At all relevant times, Henry Schein was in the business of distributing, and redistributing, pharmaceutical products to consumers with the State of Florida.

49. Cardinal Health, Inc., Henry Schein, and AmerisourceBergen are collectively referred to as the "Distributor Defendants."

50. Defendant, Cardinal Health is a Delaware corporation with its headquarters and principal place of business located in Dublin, Ohio.

51. Defendant, McKesson is a Delaware corporation with its headquarters and principal place of business located in San Francisco, California.

52. Defendant, Allergan Finance, LLC ("Allergan") is a Nevada limited liability company with its principal place of business in New Jersey. Allergan was formerly known as Actavis, Inc. and Watson Pharmaceuticals, Inc.

53. Defendant, Actavis Pharma, Inc. is a Delaware corporation with its principal place of business in New Jersey. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in New Jersey. Until they were sold to Teva Pharmaceutical Industries Ltd. in August 2016, Actavis Pharma, Inc. and Actavis LLC were part of the same corporate family as Allergan Finance, LLC and sold and marketed opioids of Allergan Finance, LLC, Actavis Pharma, Inc. and Actavis LLC.

54. Defendant, Walgreen Co. is an Illinois corporation with its principal place of business in Illinois. Defendant, Walgreen Eastern Co., Inc. is a New York corporation with its principal place of business in Illinois. Walgreen Co. and Walgreen Eastern Co., Inc. (collectively, "Walgreens") operate as a distributor of pharmaceuticals and operate a chain of retail pharmacies in Florida. Walgreens is one of the top distributors of opioids in Florida.

55. Defendant, CVS Healthcare Corp. is a Delaware corporation with its principal place of business in Rhode Island. Defendant CVS Pharmacy, Inc. is a Rhode Island corporation with a principal place of business in Rhode Island. CVS Healthcare Corp. and CVS Pharmacy, Inc. (collectively, "CVS") operates as a distributor of pharmaceuticals and operates a chain of retail pharmacies in Florida. CVS is one of the top distributors of opioids in Florida.

56. Defendant, Wal-Mart, Inc., is a Delaware corporation with its principal place of business in Arkansas. Defendant Wal-Mart Stores East, LP is a Delaware corporation with a principal place of business in Arkansas. Wal-Mart, Inc. and Wal-Mart Stores East, LP (collectively, "Wal-Mart") operate as a distributor of pharmaceuticals and operate a chain of retail pharmacies in Florida. Wal-Mart is one of the top distributors of opioids in Florida.

57. Defendant, Watson Laboratories, Inc. ("Watson") is a Nevada corporation with its principal place of business in Corona, California.

58. Defendant, Noramco, Inc. is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. Normaco, Inc. is or had been part of J&J's opium processing. It makes active pharmaceutical ingredients (APIs") for opioid painkillers.

59. Defendant, Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly owned

subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. (Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. collectively, "Par Pharmaceutical"). Par Pharmaceutical was acquired by Endo International PLC in September 2015 and is an operating company Endo International PLC.

60. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. (collectively, "Endo") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generis opioids throughout the United States.

61. Defendant, Walgreens Boots Alliance, Inc. a.k/a Walgreens Co., is an Illinois corporation with its principal place of business in Deerfield, Illinois.

62. At all times relevant to this Complaint, Walgreens distributed prescription opioids thought the United States, including in Florida.

63. Defendants have engaged in conduct and activities for many years, systematically, individually, and jointly and severally in the geographic region served by Plaintiff that have caused all of the Plaintiff's damages and all of which form the bases of the causes of action in this complaint as against Defendants. Defendants have repeatedly and systematically committed multiple torts and breaches within the geographic region served by Plaintiff.

64. Defendants, for a long time, repeatedly and systematically, have substantial contacts and business relationships with Plaintiff and Plaintiff's patients, including consensual relationships and contracts performed within Plaintiff's medical facilities, some or all of which form the bases of the causes of action alleged in this Complaint as against Defendants.

65. This Court has personal jurisdiction over Defendants, each of which has committed torts, in part or in whole, within the State of Florida and the geographic region served by Plaintiff as alleged herein. Defendants have substantial contacts and business dealings directly with Plaintiff by

virtue of their distribution, dispensing, and sales of prescription opioids. All causes of action herein relate to Defendants' wrongful actions, conduct, and omissions committed against Plaintiff, and the consequences and damages related to such wrongful actions, conduct, and omissions.

FACTUAL ALLEGATIONS

I. Over the Course of More than Two Decades, the Manufacturing Defendants Misled the Public Regarding the Dangers of Opioid Addiction and the Efficacy of Opioids for Long-Term Use, Causing Sales and Overdose Rates to Soar

66. From the mid-90s to the present, the Manufacturing Defendants (and Non-Parties) aggressively marketed and falsely promoted liberal opioid prescribing as presenting little to no risk of addiction, even when used long term for the treatment of chronic pain. Upon information and belief, they infiltrated academic medicine and regulatory agencies with sham evidence to convince doctors that treating chronic pain with long-term opioids was evidence-based medicine when, in fact, it was not. Huge profits resulted from these efforts, as did the present addiction and overdose crisis.

A. Background on Opioid Prescribing

67. The Manufacturing Defendants' (and Non-Parties') scheme to drive their rapid and dramatic expansion of prescription opioids was rooted in two pieces of so-called evidence. The first purported "evidence" was the publication of a 100-word letter to the editor published in 1980 in the *New England Journal of Medicine* ("1980 Letter to the Editor").[17] A recent article about the letter, titled "A 5-sentence letter helped trigger America's deadliest drug overdose crisis ever," quoted a 2017 study in the *New England Journal of Medicine*, in which researchers concluded:

> [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare in long-term opioid therapy. We believe that this citation pattern contributed to the North

[25] Pain: Current Understanding of Assessment, Management, and Treatments 16-17 (Dec. 2001), available at http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf (footnotes and citations omitted).

> American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy.[18]

68. The second piece of purported evidence was comprised of a single medical study published by Drs. Russell Portenoy ("Portenoy") and Kathleen Foley ("Foley") ("Portenoy Publication").[19] Portenoy emerged as one of the industry's most vocal proponents of long-term opioid use, and essentially made it his life's work to campaign for the movement to increase the use of prescription opioids. Portenoy was one of Big Pharma's[20] "thought leaders" (in effect, one of Big Pharma's aforementioned shills) and was paid to travel the country to promote more liberal prescribing for many types of pain. His talks were sponsored by the Manufacturing Defendants (and Non-Parties)and organization paid by them as continuing medical education ("CME") programs for doctors. Portenoy also had financial relationships with at least a dozen pharmaceutical companies, most of which produced prescription opioids.[21]

69. Portenoy has admitted that he minimized the risk of opioids.[22] In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not "Real" and left real evidence behind:

> I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite

---

[25] Pain: Current Understanding of Assessment, Management, and Treatments 16-17 (Dec. 2001), available at http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf (footnotes and citations omitted).

[25] Pain: Current Understanding of Assessment, Management, and Treatments 16-17 (Dec. 2001), available at http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf (footnotes and citations omitted).

[25] Pain: Current Understanding of Assessment, Management, and Treatments 16-17 (Dec. 2001), available at http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf (footnotes and citations omitted).

[25] Pain: Current Understanding of Assessment, Management, and Treatments 16-17 (Dec. 2001), available at http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf (footnotes and citations omitted).

[25] Pain: Current Understanding of Assessment, Management, and Treatments 16-17 (Dec. 2001), available at http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf (footnotes and citations omitted).

> six, seven, maybe ten different avenues of thought or avenues of evidence, *none of which represented real evidence*, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way that they hadn't before. *In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind*.[23]

70. The damage, however, was already done. The Manufacturing Defendants (and Non-Parties) used these two publications, the 1980 Letter to the Editor and the Portenoy Publication, as the foundation for a massive, far-reaching campaign to dramatically shift the thinking of healthcare providers, patients, policymakers, and the public on the risk of addiction presented by opioid therapy. By 1997, the APS and the American Academy of Pain Medicine ("AAPM") (both funded by the Manufacturing Defendants) issued a "landmark consensus," co-authored by Portenoy, stating there is little risk of action or overdose in pain patients.

71. In the years following publication of the 1980 Letter to the Editor and the Portenoy Publication, the Manufacturing Defendants (and Non-Parties) introduced powerful prescription opioids into the market. Purdue introduced MS Contin in 1987 and OxyContin in 1995; Janssen introduced Duragesic in 1990; and Cephalon's Actiq was first approved by the FDA in 1998. More recently, Endo's Opana and Opana ER were approved by the FDA in 2006; Janssen's Nucynta, approved in 2008 and Nucynta ER, approved in 2011; Cephalon's Fentora, approved in 2006; and Insys's Subsys approved in 2012.

72. These branded prescription opioids and their generic counterparts are highly addictive. Between doses, patients are likely to experience symptoms of withdrawal that include, but are in no way limited to: suffering from body aches; nausea; sweats; racing heart; hypertension;

---

[25] Pain: Current Understanding of Assessment, Management, and Treatments 16-17 (Dec. 2001), available at http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf (footnotes and citations omitted).

insomnia; anxiety; agitation; opioid cravings; and opioid induced hyperalgesia (heightened sensitivity to pain). When the agony is relieved by the next dose, it creates a cycle of dysphoria and euphoria that fosters addiction and dependence.

73. Despite the prescription opioids' highly addictive qualities, the Manufacturing Defendants launched aggressive pro-opioid marketing efforts that effected a dramatic shift in the public's and prescribers' perception of the safety and efficacy of opioids for chronic long-term pain and everyday use. In direct contravention to what doctors had previously understood about opioid risk and benefits, and for the past two decades, doctors and other health care providers have been encouraged by the Manufacturing Defendants (and Non-Parties) to prescribe opioids aggressively and were assured, based on false evidence provided directly by the Manufacturing Defendants (and Non-Parties) and numerous medical entities funded by the Manufacturing Defendants (and Non-Parties) and others with a financial stake in generating more opioid prescriptions, that (i) the risk of becoming addicted was less than 1%; and (ii) great harm was caused by "under-treated" pain." These two foundational falsehoods have led directly to the current opioid crisis.

The Defendants' (and Non-Parties') strategy was a brilliant marketing success. It was designed	2001	$38,324.56
	2002	$10,000.00
	2003	$85,180.50
	2004	$87,895.00
	2005	$244,000.00
	2006	$207,000.00
	2007	$50,000.00
	2008	$100,000.00
	Total Purdue Payments	$822,400.06
Endo	2007	$40,000.00
	2008	$100,000.00
	2009	$100,000.00
	2011	$125,000.00
	2012	$46,620.00

[25] Pain: Current Understanding of Assessment, Management, and Treatments 16-17 (Dec. 2001), available at http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf (footnotes and citations omitted).

	Total Endo Payments	$371,620.00
Cephalon	2007	$30,000.00
	2008	$100,000.00
	2011	$50,000.00
	Total Cephalon Payments	$180,000.00
Mallinckrodt	2011	$100,000.00
	Total Mallinckrodt Payments	$100,000.00

74. The letter also disclosed payments of $40,000 by Endo and $50,000 by Purdue to directly fund the production of "Responsible Opioid Prescribing" and disclosed that 42,366 copies of "Responsible Opioid Prescribing" were distributed in Florida alone.

75. **The Joint Commission:** The Joint Commission is an organization that established standards for treatment and accredits healthcare organizations in the United States. The Manufacturing Defendants, (and Non-Parties including Purdue), contributed misleading and groundless teaching materials and videos to the Joint Commission. Not surprisingly, these materials emphasized what Pharma coined the "under-treatment of pain"; referenced pain as the "fifth vital sign" (the first and only unmeasurable/subjective vital sign) that must be monitored and treated; and encouraged the use of prescription opioids for chronic pain while minimizing the danger of addiction. It also deprecated doctors' concerns about addiction as "inaccurate and exaggerated."

76. In 2000, the Joint Commission printed a book for purchase by doctors as part of required continuing education seminars that cited studies claiming "***there is no evidence that addiction is a significant issue when persons are given opioids for pain control.***" The book was sponsored by Purdue.

77. In 2001, the Joint Commission and the National Pharmaceutical Council (founded in 1953 and supported by the nation's major research-based biopharmaceutical companies) collaborated to issue a 101-page monograph titled "Pain: Current Understanding of Assessment,

Management, and Treatments." The monograph states falsely that beliefs about opioids being addictive are "erroneous":

> ***Societal issues that contribute to the undertreatment of pain include drug abuse programs and erroneous beliefs about tolerance, physical dependence, and addiction*** (see I.E.5). ***For example, some clinicians incorrectly assume that exposure to an addictive drug usually results in addiction.***
>
> * * *
>
> **b. Etiology, issue, and concerns**
>
> Many medications produce tolerance and physical dependence, and some (*e.g.* opioids, sedatives, stimulants, anxiolytics, some muscle relaxants) may cause addiction in vulnerable individuals. Most experts agree that ***patients who undergo prolonged opioid therapy usually develop physical dependence but do not develop addictive disorders. In general, patients in pain do no become addicted to opioids. Although the actual risk of addiction is unknown, it is thought to be quite low.*** A recent study of opioid analgesic use revealed "low and stable" abuse of opioids between 1990 and 1996 despite significant increases in opioids prescribed…
>
> ***Fear of causing addiction (i.e. iatrogenic addiction), particularly with opioid use, is a major barrier to appropriate pain management. This fear sometimes reflects a lack of understanding of the risk of addiction with therapeutic drug use. Although studies suggest that the risk of iatrogenic addiction is low*** (e.g., Perry and Heidrich, Zenz et al.), ***surveys indicate that clinicians often overestimate this risk.***[25]

78. Additionally, the monograph recommends that "[p]ain…is assessed in all patients" and suggests that long-acting (*i.e.* extended release) pain medications are superior and should be used whenever possible:

> ***Long-acting and sustained-release opioids are useful for patients with continuous pain, as they lessen the severity of end-of-dose pain*** and often allow the patient to sleep through the night.
>
> * * *

[25] Pain: Current Understanding of Assessment, Management, and Treatments 16-17 (Dec. 2001), available at http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf (footnotes and citations omitted).

- Administer opioids primarily via oral or transdermal routes, using long-acting medications when possible.[26]

In truth, such medications often do not last as long as promised, and there is evidence to suggest that the use of long-acting drugs may actually create more addicts.

79. The Manufacturing Defendants' (and Non-Parties') infiltration and influence over the Joint Commission's standards and literature exerted overwhelming pressure on doctors to treat and eliminate pain. As more and more doctors migrated from private practice to integrated healthcare systems in the 2000s, treatment options were dictated by, among other things, the Joint Commission's guidelines.[27] Consistent with guidelines, doctors who left pain untreated were viewed as demonstrating poor clinical skills and/or being morally compromised.[28]

80. The U.S. General Accounting Office's December 2003 Report to Congressional Requesters confirms that Purdue funded the "pain management educational courses" that taught the new standard of care for treating pain. It further revealed that Purdue disseminated educational materials on pain management, which "'facilitated [Purdue's] access to hospitals to promote OxyContin.'"[29]

81. **The American Pain Foundation**: The American Pain Foundation ("APF"), headquartered in Baltimore, Maryland, described itself as the nation's largest organization for pain patients.[30] While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from

[26] *Id.* at 38, 68 (Table 38).
[27] Lembke (2016), *supra* n.4, at 119.
[28] *Id*. at 42.
[29] Gounder, *Who Is Responsible*, *supra* n.31; U.S. General Accounting Office, GAO-04-110, *Prescription Drugs, OxyContin Abuse and Diversion and Efforts to Address the Problem* (Dec. 2003), available at https://www.gao.gov/new.items/d04110.pdf.
[30] The APF was the focus of a December investigation by ProPublica in the *Washington Post* that detailed its close ties to drugmakers.

Defendants Endo, Janssen and Cephalon and Non-Party, Purdue. It received more than $10 million in funding from opioid manufacturers between 2007 and 2012, when it shut down days after the Senate Finance Committee launched an investigation of APF's promotion of prescription opioids.

82. The APF's guides for patients, journalists and policymakers trivialized the risk of addiction, while at the same time greatly exaggerating the benefits associated with opioid painkillers.[31]

83. For example, in 2001, APF published "Treatment Options: A Guide for People Living with Pain."[32] The guide, which was produced through the support from companies including Defendant Cephalon and Non-Party, Purdue, misrepresented the risks associated with opioid use. Among other things, the guide:

- lamented that opioids were sometimes called narcotics, because ***"[c]alling opioid analgesics 'narcotics' reinforces myths and misunderstandings*** as it places emphasis on their potential abuse rather than on the importance of their use as pain medicines";[33]
- stated that "[o]pioids are an essential option for treating moderate to severe pain associated with surgery or trauma;[34] and
- opined that "[r]estricted access to the most effective medications for treating pain [opioids] is not the solution to drug abuse or addiction."[35]

The guide included blurbs from Portenoy, who is quoted as saying "[t]his is a very good resource for the pain patient," and Fishman, who is quoted as saying, "[w]hat a great job! Finally, a pill consumer resource created for patients with pain. A 'must have' for every

[31] Charles Ornstein & Tracy Weber, *American Pain Foundation Shut Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012), available at https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups.
[32] *Treatment Options: A Guide for People Living with Pain*, American Pain Foundation, available at https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.
[33] *Id.* at 11.
[34] *Id.*
[35] *Id.* at 15.

physician's waiting room."[36]

84. In 2003, APF published a newsletter titled "Best of . . . The Pain Community News" that purported to clarify any confusion over addiction and opioids and emphasized the "tragic consequence of leaving many people with severe pain under-treated because they – or their doctors – fear that opioids will cause addiction."

85. In 2009, Endo sponsored APF's publication and distribution of "Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families" ("Exit Wounds"), a book described as "the inspirational story of how one courageous veteran, with the aid of his family, recovered and thrived despite near death, traumatic brain injury, and the loss of a limb." It also purported to "offer[] veterans and their families comprehensive and authoritative information on . . . treatment options, and strategies for self-advocating for optimal pain care and medical resources inside and outside the VA system."

86. Among other false statements, Exit Wounds reported: "Long experience with opioids shows that ***people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications***." Endo, through APF, thus distributed false information with the purpose of providing veterans false information they could use to "self-advocat[e]" for opioids while omitting a discussion of the risks associated with opioid use.

87. In 2009, APF played a central role in a first-of-its-kind web-based series called "Let's Talk Pain," hosted by veteran TV journalist Carol Martin. The series brought together healthcare providers and "people with pain to discuss a host of issues from managing health care for pain to exploring integrative treatment approaches to addressing the psychological aspects associated with pain." The "Let's Talk Pain" talk show is still available online. In the very first episode of this talk

[36] *Id.* at 76.

show, the following exchange took place:

> [**Teresa Shaffer (APF Action Network Leader)**]: As a person who has been living with pain for over 20 years, opioids are a big part of my pain treatment. And I have been hearing such negative things about opioids and the risk factors of opioids. Could you talk with me a little bit about that?
>
> [**Dr. Al Anderson (AAPM Board of Directors)**]: The general belief system in the public is that the opioids are a bad thing to be giving a patient. Unfortunately, it's also prevalent in the medical profession, so patients have difficulty finding a doctor ***when they are suffering from pain for a long period of time***, especially ***moderate*** to severe pain. And ***that's the patients that we really need to sue the opioids*** methods of treatment, because they are the ones who need to have some help with the function and they're the ones that need to be controlled enough so that they can increase their quality of life.[37]

88. In reality, there is little scientific evidence to support the contention that opioids taken long-term improve function or quality of life for chronic pain patients.[38] To the contrary, there is ample evidence that opioids impose significant risks and adverse outcomes on long-term users and that they may actually reduce function.[39] As a recent article in the *New England Journal of Medicine* concluded: "Although opioid analgesics rapidly relieve many types of acute pain and improve

---

[37] *Episode 1: Safe Use of Opioids (PainSAFE)*, Let's Talk Pain (Sept. 28, 2010), https://www.youtube.com/watch?v=zeAlVAMRgsk.

[38] Lembke (2016), *supra* n.4, at 59 (citing *Agency for Healthcare Research and Quality (US): The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain*, Evid. Rep./Tech Assess., No. 218 (2014), available at https://ahrq-ehc-application.s3.amazonaws.com/media/pdf/chronic-pain-opioid-treatment_executive.pdf.

[39] Discussing the "March 2016 Guideline for Prescribing Opioids for Chronic Pain" by the Centers for Disease Control ("CDC"), doctors wrote:

> Most placebo-controlled, randomized trials of opioids have lasted 6 weeks or less, and we are aware of no study that has compared opioid therapy with other treatments in terms of long-term (more than 1 year) outcomes related to pain, function, or quality of life. The few randomized trials to evaluate opioid efficacy for longer than 6 weeks had consistently poor results. In fact, several studies have showed that use of opioids for chronic pain may actually worsen pain and functioning, possibly by potentiating pain perception.

Thomas Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501-04 (Apr. 21, 2016), available at http://www.nejm.org/doi/full/10.1056/NEJMp1515917.

function, the benefits of opioids when prescribed for chronic pain are much more questionable." The article continues, "opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions."[40]

89. The APF also developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website called www.painknowledge.org. The NIPC promoted itself as an education initiative and promoted its expert leadership team, including purported experts in the pain management field. The website painknowledge.org promised that, while using opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. In a brochure available on painknowledge.org titled "Pain: Opioid Facts," the NIPC misleadingly stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted," and even refused to rule out the use of opioid pain relievers for patients who have a history of addiction to opioids.[41]

90. In or around 2011, the APF published the "Policymaker's Guide," sponsored by Purdue, which dispels the notion that "strong pain medication leads to addiction" by characterizing it as a "***common misconception***[]":

> ***Many people living with pain, and even some health care practitioners, falsely believe that opioid pain medicines are universally addictive***. As with any medication, there are risks, but these risks can be managed when these medicines are properly prescribed and taken as directed. For more information about safety issues related to opioids and other pain therapies, visit

[40] Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, 374 New Eng. J. Med. 1253-63 (Mar. 31, 2016), http://www.nejm.org/doi/full/10.1056/NEJMra1507771#t=article.

[41] Pain: Opioid Facts, Pain Knowledge, available at https://web.archive.org/web/20101007102042/http://painknowledge.org/patiented/pdf/Patient%20Education%20b380_b385%20%20pf%20opiod.pdf (last visited Mar. 14, 2018).

http://www.painsafe.org.[42]

91. The guide describes "pain in America" as "an evolving public health crisis" and characterizes concerns about opioid addiction as misconceptions: "Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include: . . . ***Misconceptions about opioid addiction***." [43] It even characterizes as a "***myth***" that "***[c]hildren can easily become addicted to pain medications***."[44] The guide further asserts that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health and health-related quality of life for chronic pain patients, which was not the case.[45]

92. In December 2011, the *Washington Post* reported on ProPublica's investigation of the APF, which detailed APF's close ties to drugmakers:

> ***[T]he pills continue to have an influential champion in the American Pain Foundation***, which describes itself as the nation's largest advocacy group for pain patients. ***Its message: The risk of addiction is overblown, and the drugs are underused***.
>
> What the nonprofit organization doesn't highlight is the money behind that message.
>
> ***The foundation collected nearly 90 percent of its $5 million in funding last year from the drug and medical-device industry – and closely mirrors its positions***, an examination by ProPublica found.[46]

---

[42] *A Policymaker's Guide to Understanding Pain & Its Management*, American Pain Foundation at 5, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last visited Mar. 08, 2018).
[43] *Id*. at 6.
[44] *Id*. at 40.
[45] The "Policymaker's Guide" cites for support "Opioids for chronic noncancer pain: a meta- analysis of effectiveness and side effects," a review published in 2006 in the *Canadian Medical Association Journal*. *Id*. at 34. However, the review concludes: "For functional outcomes, ***the other analgesics were significantly more effective than were opioids***." Andrea D. Furlan, *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Canadian Med. Assoc. J. 1589-94 (May 23, 2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1459894/. The Purdue-sponsored guide failed to disclose both this conclusion and the fact that the review analyzed studies that lasted, on average, five weeks and therefore could not support the long-term use of opioids.
[46] Charles Ornstein & Tracy Weber, *Patient advocacy group funded by success of painkiller drugs, probe finds*, Wash. Post (Dec. 23, 2011), available at https://www.washingtonpost.com/national/healthscience/patient-advocacy-group-funded-by-success-of-

93. **American Academy of Pain Medicine and American Pain Society:** The Manufacturing Defendants, including at minimum Endo, Janssen and Purdue, have for decades contributed funding to the AAPM and the APS.

94. In 1997, the AAPM issued a "consensus" statement that endorsed the use of opioids for the treatment of chronic pain and claimed further that the risk of patient addiction to opioids was low. The chairman of the committee that issued the statement, Haddox, was at the time a paid speaker for Purdue. Haddox was later hired as Purdue's vice president for health policy. The consensus statement, which also formed the foundation of the 1998 guidelines, was published on the AAPM's website. AAPM's corporate council includes Purdue, Depomed, Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Fishman (2005), Dr. Perry G. Fine ("Fine") (2011) and Lynn R. Webster ("Webster") (2013), all of whom have connections to the opioid manufacturers as well documented below.

95. At or about the same time, the APS introduced the "pain as the 5th vital sign" campaign, followed soon thereafter by the U.S. Department of Veterans Affairs adopting that campaign as part of their national pain management strategy.

96. AAPM and APS issued guidelines in 2009 ("2009 Guidelines") that continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines received funding from Defendants Janssen, Cephalon, Endo or Non-Party, Purdue.

97. The 2009 Guidelines falsely promoted opioids as safe and effective for treating chronic pain and concluded that the risk of addiction was manageable for patients regardless of past

painkiller-drugs-probefinds/2011/12/20/gIQAgvczDP_story.html?utm_term. 22049984c606.

abuse histories.[47] The 2009 Guidelines have proved to be a particularly effective channel of deception, and have influenced not only treating physicians but also the body of scientific evidence on opioids. They were reprinted in the journal *Pain*, have been cited hundreds of times in academic literature, and remain available online. The Manufacturing Defendants (and Non-Parties) widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions.

98. **The Alliance for Patient Access ("APA")**: Founded in 2006, APA is a self-described patient advocacy and health professional organization that styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care."[48] It is run by Woodberry Associates, a lobbying firm that was also established in 2006.[49] As of June 2017, the APA listed 30 "Associate Members and Financial Supporters." The list includes Johnson & Johnson, Endo, Mallinckrodt, Purdue and Cephalon.

99. APA's board members have also received substantial funding directly from pharmaceutical companies.[50] For instance, board vice president Srinivas Nalamachu, M.D., who practices in Kansas, received more than $800,000 from 2013 through 2015 from pharmaceutical companies – nearly all of it from manufacturers of opioids or drugs that treat opioids' side-effects, including from Defendants Endo and Cephalon and Non-Parties, Purdue and Insys. In 2017, Dr.

---

[47] Roger Chou, *et al*., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non- Cancer Pain*, 10(2) J. Pain 113 (Feb. 2009), available at http://www.jpain.org/article/S1526-5900(08)00831-6/pdf (hereinafter "Chou, *Clinical Guidelines*").

[48] The Alliance for Patient Access, *About AfPA*, http://allianceforpatientaccess.org/about-afpa/ (last visited Mar. 08, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

[49] Mary Chris Jaklevic, *Non-profit Alliance for Patient Access Uses Journalists and Politicians to Push Big Pharma's Agenda*, Health News Review (Oct. 2, 2017), available at https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/ (hereinafter "Jaklevic, *Non-profit Alliance for Patient Access*").

[50] All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica's Dollars for Docs database, available at https://projects.propublica.org/docdollars/.

Nalamachu's clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys.[51] Other board members include Dr. Robert A. Yapundich from North Carolina, who, between 2013 and 2015, received $215,000 from pharmaceutical companies including Defendant Cephalon and Non-Party Mallinckrodt; Dr. Jack D. Schim from California, who received more than $240,000 between 2013 and 2015 from pharmaceutical companies including Defendants Endo and Cephalon and Non-Party Mallinckrodt; Dr. Howard Hoffberg, a Maryland doctor who received $153,000 between 2013 and 2015 from pharmaceutical companies including Defendants Endo and Cephalon, and Non-Parties, Purdue, Insys, Mallinckrodt; and Dr. Robin K. Dore, a California physician who received $700,000 between 2013 and 2015 from various pharmaceutical companies.

100. Among its other activities, APA issued a white paper titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse."[52] The white paper, *inter alia*, criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

> Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.
>
> * * *
>
> In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and

[51] Andy Marso, *FBI seizes records of Overland Park pain doctor tied to Insys, Kansas City Star* (July 20, 2017), http://www.kansascity.com/news/business/health-care/article162569383.html.

[52] *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse, Institute for Patient Access* (Oct. 2013), available at http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf.

> may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives.
>
> * * *
>
> We cannot merely assume that these programs will reduce prescription pain medication use and abuse.

101. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

> Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.

102. In addition, in an echo of earlier industry efforts to push back against what they termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication:

> Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management – a situation fueled by the numerous regulations and fines that surround prescription pain medications.

103. In conclusion, the white paper states that "Prescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs."

104. The APA also issues "Patient Access Champion" financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a $7.8 million donation

from unnamed donors. While the awards are ostensibly given for protecting patients' access to Medicare, and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they appear to be given to provide cover to and reward members of Congress who have supported the APA's agenda.[53]

105. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the U.S. Drug Enforcement Administration ("DEA") to police pill mills by enforcing the "suspicious orders" provision of the CSA.[54] The AAPM is also a signatory to this letter. An internal Department of Justice ("DOJ") memo stated that the proposed bill "could actually result in increased diversion, abuse, and public health and safety consequences"[55] and, according to DEA chief administrative law judge John J. Mulrooney, the law would make it "all but logically impossible" to defend prosecutions of manufacturers and distributors, like the Defendants here, in the federal courts.[56] The law passed both houses of Congress and was signed into law in 2016.

1. *The Manufacturing Defendants Paid Key Opinion Leaders and Sponsored Speakers' Bureaus to Disseminate False and Misleading Messaging*

106. The Manufacturing Defendants (and Non-Parties) have paid millions of dollars to physicians to promote aggressive prescribing of opioids for chronic pain. Recently released federal data shows that the Manufacturing Defendants (and Non-Parties) increased such payments to physicians

[53] Jaklevic, *Non-profit Alliance for Patient Access*, *supra* n.73.
[54] Letter from Alliance for Patient Access, *et al*., to Congressmen Tom Marino, Marsha Blackburn, Peter Welch, and Judy Chu (Jan. 26, 2015), http://webcache.googleusercontent.com/search?q=cache:-poWY1gKeEgJ:allianceforpatientaccess.org/wp-content/uploads/2013/12/FINAL-Patient-Access-Letter-of-Support-House-Bill.pdf+&cd=1&hl=en&ct=clnk&gl=us. (last available source).
[55] Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS News (Oct. 17, 2017),https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/.
[56] John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 MARQ. L. REV. 333 (2017), available at http://scholarship.law.marquette.edu/cgi/viewcontent.cgi?article=5348&context=mulr.

who treat chronic pain even while the opioid crisis accelerated and overdose deaths from prescription opioids and related illicit drugs, such as heroin, soared to record rates.[57] These payments come in the form of consulting and speaking fees, free food and beverages, discount coupons for drugs, and other perks and freebies. The total payments from the Manufacturing Defendants (and Non-Parties) to doctors related to opioids doubled from 2014 to 2015. Moreover, according to experts, research shows even small amounts of money can have large effects on doctors' prescribing practices.[58] Physicians who are high prescribers are more likely to be invited to participate in Defendants' speakers' bureaus. According to a study published by the U.S. National Institutes of Health, "[i]n the speakers' bureau system, physicians are recruited and trained by pharmaceutical, biotechnology, and medical device companies to deliver information about products to other physicians, in exchange for a fee."[59]

107. The use of speakers' bureaus has led to substantial ethical concerns within the medical field. According to a 2013 publication by the Institute on Medicine as a Profession, speakers' bureaus are ethically compromised because they often present information as objective when it is heavily biased toward the interests of the industry sponsor and, in fact, may lead to the dissemination of false or biased information. These findings are substantiated by citations to research in the *Journal of the American Medical Association*, *The Journal of Law*, *Medicine & Ethics,* and *Academic Psychiatry*.

[57] Joe Lawlor, *Even amid crisis, opioid makers plied doctors with perks*, Portland Press Herald (Dec. 25, 2016), available at https://www.pressherald.com/2016/12/25/even-amid-crisis-opioid-makers-plied-doctors-with-perks/.
[58] *Id.*
[59] Lynette Reid & Matthew Herder, *The Speakers' bureau system: a form of peer selling*, 7(2) Open Med. e31-e39 (Apr. 2, 2013), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3863750/.

> **The Problem:**
>
> **Pharmaceutical companies often recruit physicians to perform speeches or presentations for the purpose of marketing a specific drug. In 2010, 8.6% of physicians reported having received payments for participating in speakers' bureaus**. *These speakers' bureaus leverage the credibility of physicians in order to promote the use of pharmaceutical products.* **The physicians are generally trained to present a certain message, or are provided with pre-produced slides. The audience may assume that these presentations are objective, when in fact they are heavily biased towards the interests of the industry sponsor**.
>
> ***Speakers' bureaus may lead to the dissemination of false or biased information.*** Exposure to industry-sponsored speaking events is associated with decreased quality of prescribing. Additionally, the compensation provided for these engagements may influence the attitudes or judgment of the presenter.[60]

108. For example, Fishman is a physician whose ties to the opioid drug industry are legion. He has served as an APF board member, president of the AAPM, and has participated yearly in numerous CME activities for which he received "market rate honoraria." As discussed above, Fishman has authored publications, including the seminal guides on opioid prescribing, that were funded by the Manufacturing Defendants (and Non-Parties). He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. Fishman himself has acknowledged his failure to disclose all of his potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled "Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion."[61]

109. Similarly, Fine's ties to the Manufacturing Defendants (and Non-Parties) are well

---

[60] *Speakers' Bureaus: Best Practices for Academic Medical Centers*, IMAP (Oct. 10, 2013), available at http://imapny.org/wp-content/themes/imapny/File%20Library/Best%20Practice%20toolkits/Best-Practices_Speakers--bureaus.pdf.

[61] Scott M. Fishman, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306(13) JAMA 1445 (2011); Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011), available at https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry (hereinafter "Weber, *Two Leaders in Pain*").

documented.[62] He has authored articles and testified in court cases and before state and federal committees, and like Fishman, has served as president of the AAPM and argued against legislation restricting high-dose opioid prescription for non-cancer patients. Multiple videos also feature Fine delivering educational talks about prescription opioids; he even testified at trial that the 1,500 pills per month prescribed for pain to celebrity Anna Nicole Smith did not make her an addict before her death from an overdose.[63] Fine has also acknowledged failing to disclose numerous conflicts of interest.

110. Fishman and Fine are just two of the many physicians whom the Manufacturing Defendants (and Non-Parties) paid to present false or biased information on the use of opioids for chronic pain.

2. Senate Investigations of Manufacturing Defendants

111. In May 2012, the Chair and Ranking Members of the Senate Finance Committee, Max Baucus (D-MT) and Chuck E. Grassley (R-IA), launched an investigation into makers ofnarcotic painkillers and the groups that champion them. The investigation was triggered by "an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers," including popular brand names like OxyContin, Vicodin and Opana.

112. The Senate Finance Committee sent letters to Purdue, Endo and Johnson & Johnson, as well as to five groups that support pain patients, physicians or research, including the APF, AAPM, APS, the University of Wisconsin Pain & Policy Studies Group and the Center for Practical Bioethics. Letters also went to the FSMB and the Joint Commission.

113. As shown below in an excerpt from the Senators' letter to APF, the Senators

[62] Weber, *Two Leaders in Pain*, *supra* n.85.
[63] Linda Deutsch, *Doctor: 1,500 pills don't prove Smith was addicted*, Seattle Times (Sept. 22, 2010, 5:16 PM), available at https://www.seattletimes.com/entertainment/doctor-1500-pills-dont-prove-smith-was-addicted/.

addressed the magnitude of the epidemic and asserted that mounting evidence supports that the pharmaceutical companies may be responsible:

> ***It is clear that the United States is suffering from an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers such as Oxycontin (oxycodone), Vicodin (hydrocodone), Opana (oxymorphone)***. According to CDC data, "more than 40% (14,800)" of the "36,500 drug poisoning deaths in 2008" were related to opioid-based prescription painkillers. Deaths from these drugs rose more rapidly, "from about 4,000 to 14,800" between 1999 and 2008, than any other class of drugs, [killing] more people than heroin and cocaine combined. ***More people in the United States now die from drugs than car accidents as a result of this new epidemic. Additionally, the CDC reports that improper "use of prescription painkillers costs health insurers up to $72.5 billion annually in direct health care costs."***
>
> * * *
>
> Concurrent with the growing epidemic, The *New York Times* reports that, based on federal data, ***"over the last decade, the number of prescriptions for the strongest opioids has increased nearly fourfold, with only limited evidence of their long-term effectiveness or risks" while "[d]ata suggest that hundreds of thousands of patients nationwide may be on potentially dangerous doses."***
>
> ***There is growing evidence pharmaceutical companies that manufacture and market opioids may be responsible, at least in part, for this epidemic by promoting misleading information about the drugs' safety and effectiveness.*** Recent investigative reporting from the *Milwaukee Journal Sentinel/MedPage Today* and *ProPublica* revealed extensive ties between companies that manufacture and market opioids and non-profit organizations such as the American Pain Foundation, the American Academy of Pain Medicine, the Federation of State Medical Boards, and University of Wisconsin Pain and Policy Study Group, and the Joint Commission.
>
> In a *ProPublica* story published in The *Washington Post*, the watchdog organization examined the ***American Pain Foundation, a "health advocacy" organization that received "nearly 90 percent of its $5 million funding from the drug and medical device industry."*** *ProPublica* wrote that its review of the American Pain Foundation's "guides for patients, journalists, and policymakers ***play down the risks associated with opioids and exaggerate their benefits.*** Some of the foundation's materials on the drugs include statements that are misleading or based on scant or disputed research."
>
> According to the *Milwaukee Journal Sentinel/MedPage Today*, a ***"network of national organizations and researchers with financial***

> ***connections to the makers of narcotic painkillers . . . helped create a body of dubious information" favoring opioids "that can be found in prescribing guidelines, patient literature, position statements, books and doctor education courses."***[64]
>
> Although it is critical that patients continue to have access to opioids to treat serious pain, ***pharmaceutical companies and health care organizations must distribute accurate and unbiased information about these drugs in order to prevent improper use and diversion to drug abusers***.[65]

114. The Senators demanded substantial discovery, including payment information from the companies to various groups, including the front organizations identified above, and to physicians, including Portenoy, Fishman and Fine, among others. The letter asked, *inter alia*, about any influence the companies exerted on the creation of a 2004 pain guide for physicians distributed by the FSMB, on the APS's guidelines, and on the APF's Military/Veterans Pain Initiative. Almost immediately upon the launch of the Senate investigation, the APF shut down "due to irreparable economic circumstances." The opioid report resulting from this investigation has not been released to the public.[66]

115. On March 29, 2017, it was widely reported[67] that yet another Senate investigation had been launched:

> Missouri Senator Claire McCaskill has launched an investigation into some of the country's leading prescription drug manufacturers, demanding documents and records dating back the past five years which indicate just

---

[64] For example, the *Sentinel* reported that the FSMB, with financial support from opioid manufacturers, distributed "[m]ore than 160,000 copies" of a model policy book that drew criticism from doctors because "it failed to point out the lack of science supporting the use of opioids for chronic, non cancer pain." John Fauber, *Follow the Money: Pain, Policy, and Profit*, MedPage Today (Feb. 19, 2012), available at http://www.medpagetoday.com/Neurology/PainManagement/31256.

[65] Letter from U.S. Senators Charles E. Grassley and Max Baucus to Catherine Underwood, Executive Director (May 8, 2012), American Pain Society, available at https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American%20Pain%20Society.pdf (footnote added).

[66] Paul D. Thacker, *Senators Hatch and Wyden: Do your jobs and release the sealed opioids report*, Stat News (June 27, 2016), available at https://www.statnews.com/2016/06/27/opioid-addiction-orrin-hatch-ron-wyden/; *see also* Ornstein, *American Pain Foundation*, *supra* n.55.

[67] Nadia Kounang, *Senator opens investigation into opioid manufacturers*, CNN (Mar. 29, 2017), available at http://www.cnn.com/2017/03/28/health/senate-opioid-manufacturer-investigation/index.html.

> what the companies knew of the drugs' risk for abuse as well as documents detailing marketing practices and sales presentations. Her office has sent letters to the heads of Purdue, Janssen/Johnson & Johnson, Insys, Mylan, and Depomed.

The above-referenced companies were reported targeted based on the role in manufacturing some of the opioid painkillers with the highest sales in 2015.

116. On September 6, 2017, Senator McCaskill's report, "Fueling an Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior Authorization," was published. The report found that Insys manipulated the prior authorization process by misleading pharmacy benefit managers about the role of Insys in the prior authorization process and the presence of breakthrough cancer pain in potential Subsys patients.[68]

117. On September 12, 2017, Senator McCaskill convened a Roundtable Discussion on Opioid Marketing. During the hearing, Senator McCaskill stated:

> The opioid epidemic is the direct result of a calculated marketing and sales strategy developed in the 90's, which delivered three simple messages to physicians. First, that chronic pain was severely undertreated in the United States. Second, that opioids were the best tool to address that pain. And third, that opioids could treat pain without risk of serious addiction. As it turns out, these messages were exaggerations at best and outright lies at worst.
>
> * * *
>
> Our national opioid epidemic is complex, but one explanation for this crisis is simple, pure greed.

118. Professor Adriane Fugh-Berman ("Fugh-Berman"), Associate Professor at Georgetown University Medical Center and director of a program at Georgetown called Pharmed Out, which conducts research on and educates the public about inappropriate pharmaceutical company marketing, also testified during the hearing. She, too, placed the blame for the opioid crisis

[68] HSGAC Minority Staff Report, Insys Therapeutics and the Systemic Manipulation of Prior Authorization (2017).

squarely at the feet of pharmaceutical companies:

> Since the 1990's, pharmaceutical companies have stealthily distorted the perceptions of consumers and healthcare providers about pain and opioids. Opioid manufacturers use drug reps, physicians, consumer groups, medical groups, accreditation and licensing bodies, legislators, medical boards and the federal government to advance marketing goals to sell more opioids. These aggressive marketing pushes resulted in hundreds of thousands of deaths from the overprescribing of opioids. The U.S. is about – comprises about five percent of the world population, but we use about two-thirds of the world supply of opioids.

119. Fugh-Berman also answered why doctors were able to be convinced by pharmaceutical companies' marketing efforts:

> Why did the physicians fall for this? Well, physicians are overworked, overwhelmed, buried in paperwork and they feel unappreciated. Drug reps are cheerful. They're charming. They provide both appreciation and information. Unfortunately, the information they provide is innately unreliable.
>
> Pharmaceutical companies influence healthcare providers' attitudes and their therapeutic choices through financial incentives that include research grants, educational grants, consulting fees, speaking fees, gifts and meals.

120. Fugh-Berman further described the false information provided by pharmaceutical companies and the industry creation of front organizations, including the APF, to pass industry-influenced regulations and policies:

> Pharmaceutical companies convinced healthcare providers that they were opiophobic and that they were causing suffering to their patients by denying opioids to patients with back pain or arthritis. They persuaded prescribers that patients with pain were somehow immune to addiction. Even when addiction was suspected, physicians were taught that it might not really be addiction, it might be pseudo- addiction, an invented (ph) condition that's treated by increasing opioid dosages.
>
> Industry created the American Pain Foundation co-opted other groups including medical organizations, and they change state laws to eliminate curbs on opioid prescribing. Between 2006 and 2015, pharmaceutical companies and the advocacy groups they control employ 1,350 lobbyists a year in legislative hubs. Industry-influenced regulations and policies ensure that hospitalized patients were and are berated paraded (?) constantly about their level of pain and overmedicated with opioids for that pain. Even a week

> of opioids can lead a patient into addiction so many patients are discharged from hospitals already dependent on opioids.

121. In addition, Fugh-Berman pointed out that promotion of opioids remains ongoing despite increasing public concern about their use:

> Promotion of opioids is not in the past. Between 2013 and 2015, one in 12 physicians took out money from opioid manufacturers, a total of more than $46 million. Industry-friendly messages that pharmaceutical companies are currently perpetuating reassure physicians that prescribing opioids is safe as long as patients do not have a history of substance abuse or mental illness.

122. Fugh-Berman concluded by stating: "It is a misperception to think that most opioid deaths are caused by misuse of opioids or overdoses. In fact, many deaths occur when people are using opioids in exactly the way they were prescribed. Misuse isn't the problem; use is the problem."

B. The Devastating Impact

123. The impact of the Manufacturing Defendants' (and Non-Parties') false messaging has been profound. The drug companies profited handsomely as more and more people became addicted to opioids and died of overdoses.[69]

124. For Purdue, sales grew from $48 million per year in 1996, to over $1 billion per year in 2000, to $3.1 billion per year ten years later. In 2011, pharmaceutical companies generated revenues of $11 billion from opioid sales alone.

125. The United States, including specifically the geographic region served by Plaintiff, is experiencing an unprecedented opioid addiction and overdose epidemic, costing millions of dollars for, *inter alia*, treatment, services and public safety, as well as lost productivity in the workforce, economic opportunity and tax revenue.

126. By 2002, "[l]ifetime ***nonmedical*** use of OxyContin increased from 1.9 million to 3.1

[69] German Lopez, *How big pharma got people hooked on dangerous opioids – and made tons of money off it*, Vox (Sept. 22, 2016), available at http://www.vox.com/2016/2/5/10919360/opioid-epidemic-chart.

million people between 2002 and 2004, and in 2004 there were 615,000 new nonmedical users of OxyContin."[70]

127. By 2004, OxyContin had "become the most prevalent prescription opioid abused in the United States."[71] The severity of the problem was first felt in states including Maine, West Virginia, eastern Kentucky, southwestern Virginia and Alabama, where, from 1998 through 2000, hydrocodone and oxycodone were being prescribed 2.5-5 times more often than the national average. By 2000, these same areas had a prescription rate up to 5-6 times higher than the national average. These areas were also the first to suffer increased abuse and diversion, which became apparent by 1999 and 2000. Manufacturers then expanded the geographic market by investing hundreds of millions of dollars in marketing, and the once-regional problem began to spread nationally. "[B]y 2004 OxyContin had become a leading drug of abuse in the United States."[72]

128. As OxyContin sales grew between 1999 and 2002, so did sales of other opioids, including fentanyl (226%), morphine (73%) and oxycodone (402%). And, as prescriptions surged between 1999 and 2010, so did deaths from opioid overdoses (from about 4,000 to almost 17,000).[73]

129. In 2012 alone, an estimated 259 million opioid prescriptions were filled, enough to medicate every adult in the United States for a month on a round-the-clock basis.[74] In 2014, there were more than 47,000 drug overdose deaths nationwide, 61% involving a prescription or illicit opioid.[75] The use of prescription painkillers cost health insurers up to $72.5 billion annually in direct

[70] Van Zee, *Promotion and Marketing*, *supra* n.26.
[71] *Id.*
[72] *Id.*
[73] Gounder, *Who Is Responsible*, *supra* n.31.
[74] *Opioid Painkiller Prescribing*, Centers for Disease Control and Prevention: Vital Signs (July 2014), available at https://www.cdc.gov/vitalsigns/opioid-prescribing/.
[75] Rudd, *Increases in Drug and Opioid-Involved Overdose*, *supra* n.2.

healthcare costs.[76]

130. According to the CDC, drug overdose deaths in Florida increased by 4.8% from 2013 to 2014, and by 22.7% from 2014 to 2015, with deaths increasing from 2,474, to 2,634, to 3,228 over the three-year period, with opioids being the main driver of those deaths. During that timeframe, drug overdose deaths in Florida increased from approximately 12 per 100,000 to 16 per 100,000. Further, the Florida Medical Examiners Commission's 2016 Interim Report indicates that between January and June 2016, 33.8% of decedents examined had opioids in their system at the time of death.

131. Lee County has seen a corresponding rise in area opioid usage and accidental deaths.

II. The Manufacturing Defendants' Specific Unlawful Practices

A. Non-Party, Purdue

132. Non-Party, Purdue, which is privately held by the Sackler family – one of America's richest families with a collective net worth of $13 billion—manufactures, markets, sells and distributes opioids in the geographic region served by Plaintiff and nationwide, including the following:

OxyContin (oxycodone hydrochloride extended release)	Opioid agonist[77] indicated for pain severe enough to require daily, around-the-clock, long-term opioid treatment; not indicated as an as-needed (p.r.n.) analgesic. It was first approved by the FDA in December 1995.	Schedule II
MS Contin (morphine sulfate extended release)	Opioid agonist; controlled-release tablet form of morphine sulfate indicated for the management of severe pain; not intended for use as a p.r.n. analgesic; first approved in May 1987 as the first formulation of an opioid pain medicine that allowed dosing every 12	Schedule II

[76] Katherine Eban, *OxyContin: Purdue Pharma's painful medicine*, Fortune Magazine (Nov. 9, 2011), available at http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/ (hereinafter "Eban, *Painful Medicine*").

[77] An "agonist" medication is one that binds to and fully activates targeted receptors in the brain. They activate these neurotransmitter receptors to illicit a certain response. An "antagonist" medication, on the other hand, works to prevent the binding of other chemicals to neurotransmitters in order to block a certain response. Both may be used to offer pain relief. *Health Q&A*, Reference*, https://www.reference.com/health/difference-between-agonist-antagonist-drugs-838e9e0994a788eb (last visited Mar. 08, 2018).

	hours.	
Dilaudid (hydromorphone hydrochloride)	Opioid analgesic; injectable and oral formulation; eight times more potent than morphine.[78]	Schedule II
Dilaudid-HP (hydromorphone hydrochloride)	Opioid analgesic; injectable and oral high-potency and highly concentrated formulation indicated for relief of moderate-to-severe pain in opioid-tolerant patients.	Schedule II
Hysingla ER (hydrocodone bitrate)	Brand-name extended-release form of hydrocodone bitrate that is indicated for the management of severe pain.	Schedule II
Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride)	Brand-name extended-release opioid analgesic made of a combination of oxycodone hydrochloride and naloxone hydrochloride. It was approved by the FDA on July 23, 2013.	Schedule II

1. Purdue Falsely Marketed Extended-Release Drugs as Safer and More Effective than Regular-Release Drugs

133. Non-Party, Purdue launched OxyContin 20 years ago with a bold marketing claim: "One dose relieves pain for 12 hours, more than twice as long as generic medications."[79] Prior to launching OxyContin, Purdue conducted focus groups with doctors and "learned that the 'biggest negative' that might prevent widespread use of the drug was ingrained concern regarding the 'abuse potential' of opioids."[80] In its initial press release launching the drug, Purdue told doctors that one OxyContin tablet would provide "smooth and sustained pain control all day and all night." Based in large part on that promise, and Purdue's repeated assurances that opioids were both effective and

[78] *Dilaudid Addiction*, Suboxone California, https://www.suboxonecalifornia.com/suboxone-treatment/dilaudid-addiction/ (last visited Mar. 08, 2018).
[79] Harriet Ryan, *et al.*, *"You Want A Description of Hell?" OxyContin's 12-Hour Problem*, *L.A. Times* (May 5, 2016), available at http://www.latimes.com/projects/oxycontin-part1/ (hereinafter "Ryan, *Description of Hell*").
[80] Keefe, *Empire of Pain*, *supra* n.4.

non-addictive, OxyContin became America's bestselling painkiller.[81] But, Purdue had no evidentiary basis for those claims.[82]

134. In truth, Non-Party, Purdue's nationwide marketing claims were false and highly deceptive. OxyContin was not superior to immediate-release opioids. And not only does OxyContin wear off early, as Purdue's own early studies showed, it is highly addictive:

> OxyContin's stunning success masked a fundamental problem: The drug wears off hours early in many people, a Los Angeles Times investigation found. ***OxyContin is a chemical cousin of heroin, and when it doesn't last, patients can experience excruciating symptoms of withdrawal, including an intense craving for the drug.***[83]

135. Furthermore, experts call the 12-hour dosing "'an addiction producing machine.'"[84] Purdue had reportedly known for decades that it falsely promised 12-hour relief and nevertheless mobilized hundreds of sales representatives to "refocus" physicians on 12-hour dosing:

> - …Even before OxyContin went on the market, ***clinical trials showed many patients weren't getting 12 hours of relief***. Since the drug's debut in 1996, the company has been confronted with additional evidence, including complaints from doctors, reports from its own sales reps and independent research.
>
> - The company has held fast to the claim of 12-hour relief, in part to protect its revenue. OxyContin's market dominance and its high price – up to hundreds of dollars per bottle – hinge on its 12-hour duration. Without

---

[81] Press Release, Purdue Pharma L.P., New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain (May 31, 1996), available at http://documents.latimes.com/oxycontin-press-release-1996/.

[82] Though the FDA's 1995 approval allowed Purdue to include a package insert for OxyContin declaring the drug to be safer than its competitors due to its delayed release design, Purdue had in fact "conducted no clinical studies on how addictive or prone to abuse the drug might be. . . . The F.D.A. examiner who oversaw the process, Dr. Curtis Wright, left the agency shortly afterward. Within two years, he had taken a job at Purdue." Keefe, *Empire of Pain*, *supra* n.4.

[83] The *Los Angeles Times* investigation, reported in three parts on May 5, July 10 and December 18, 2016, included the review of thousands of pages of confidential Purdue documents and court and other records. They span three decades, from the conception of OxyContin in the mid-1980s to 2011, and include e-mails, memoranda, meeting minutes and sales reports, as well as sworn testimony by executives, sales representatives and other employees. Ryan, *Description of Hell*, *supra* n.110. The *Los Angeles Times* reporters also examined FDA records, Patent Office files and medical journal articles, and interviewed experts in pain treatment, addiction medicine and pharmacology. *Id.*

[84] Frydl, *Purdue Pharma*, *supra* n.3.

that, it offers little advantage over less expensive painkillers.

- When many doctors began prescribing OxyContin at shorter intervals in the late 1990s, Purdue executives mobilized hundreds of sales reps to "refocus" physicians on 12-hour dosing. Anything shorter "needs to be nipped in the bud. NOW!!" one manager wrote to her staff.

- Purdue tells doctors to prescribe stronger doses, not more frequent ones, when patients complain that OxyContin doesn't last 12 hours. That approach creates risks of its own. Research shows that the more potent the dose of an opioid such as OxyContin, the greater the possibility of overdose and death.

- More than half of long-term OxyContin users are on doses that public health officials consider dangerously high, according to an analysis of nationwide prescription data conducted for The Times.[85]

136. As reported by *The New York Times*, "internal Purdue Pharma documents show that company officials recognized even before the drug was marketed that they would face stiff resistance from doctors who were concerned about the potential of a high-powered narcotic like OxyContin to be abused by patients or cause addiction." To combat this resistance, Purdue falsely promised the long-acting, extended-release formulation was safer and "less prone to such problems."[86]

2. Non-Party, Purdue Falsely Marketed Low Addiction Risk to Wide Swaths of Physicians

137. In addition to pushing OxyContin as safe and non-addictive by equating extended-release with a lower risk, Non-Party, Purdue also promoted the use of prescription opioids for use in non-cancer patients, who make up 86% of the total opioid market today.[87]

138. Rather than targeting merely those physicians treating acute severe short-term (like post-operative) pain or oncologists treating end-stage cancer pain, reports indicate that Purdue heavily promoted OxyContin nationwide to doctors including general practitioners, who often had

[85] Ryan, *Description of Hell*, *supra* n.110.
[86] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, *N.Y. Times* (May 10, 2007), available at http://www.nytimes.com/2007/05/10/business/11drug-web.html (hereafter "Meier, *GuiltyPlea*").
[87] Ornstein, *American Pain Foundation*, *supra* n.55.

little training in the treatment of serious pain or in recognizing signs of drug abuse in patients.[88] According to a report in *The New Yorker*, "[a] major thrust of the sales campaign was that OxyContin should be prescribed not merely for the kind of severe short-term pain associated with surgery or cancer but also for less acute, longer-lasting pain: arthritis, back pain, sports injuries, fibromyalgia" and "[t]he number of conditions that OxyContin could treat seemed almost unlimited."[89]

139. Sales representatives plied these and other physicians with coupons that were redeemable for a 7- to 30-day supply of free OxyContin, a Schedule II narcotic that by definition cannot be prescribed for more than one month at a time, with the promise that OxyContin was a safe opioid. Purdue "trained its sales representatives to carry the message that the risk of addiction was 'less than one percent,'" and "[a] consistent feature in the promotion and marketing of OxyContin was a systematic effort to minimize the risk of addiction in the use of opioids for the treatment of chronic non-cancer-related pain."[90]

140. Sales representatives marketed OxyContin as a product "'to start with and to stay with,'" and Non-Party, Purdue deliberately exploited a misconception it knew many doctors held that oxycodone was less potent than morphine.[91] They also received training in overcoming doctors' concerns about addiction with talking points they knew to be untrue about the drug's abuse potential. *The New Yorker* reported that "[i]n 2002, a sales manager from the company, William Gergely, told a state investigator in Florida that Purdue executives 'told us to say things like it is "virtually" non-addicting.'"[92]

---

[88] Meier, *Guilty Plea*, *supra* n.117.
[89] Keefe, *Empire of Pain*, *supra* n.4.
[90] Van Zee, *Promotion and Marketing*, *supra* n.26.
[91] Keefe, *Empire of Pain*, *supra* n.4.
[92] *Id.*

141. Further, "[a]ccording to training materials, Non-Party, Purdue instructed sales representatives to assure doctors – repeatedly and without evidence – that 'fewer than one per cent' of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)"[93]

142. Even as late as 2015, and perhaps even later, Purdue sales representatives were telling physicians OxyContin was addiction resistant and had "'abuse-deterrent' properties."[94]

143. And the marketing worked. Keith Humphreys, Professor of Psychiatry at Stanford and drug-policy adviser to the Obama Administration, said

> That's the real Greek tragedy of this – that so many well-meaning doctors got co-opted. The level of influence is just mind-boggling. Purdue gave money to continuing medical education, to state medical boards, to faux grassroots organizations.[95]

144. Additionally, Non-Party Purdue tracked physicians' prescribing practices by reviewing pharmacy prescription data it obtained from I.M.S. Health, a company that buys bulk prescription data from pharmacies and resells it to drug makers for marketing purposes (and which, notably, Arthur Sackler is a co-founder). Rather than reporting highly suspicious prescribing practices, Non-Party Purdue used the data to track physicians who prescribed opioids and might be persuaded to increase their opioid prescription volume. Purdue also could identify physicians writing large numbers of prescriptions, and particularly for high-dose 80 mg pills – potential signs of

[93] *Id.*
[94] *Id.*
[95] *Id.*

diversion and drug dealing.[96] Purdue called those high- prescribing doctors "whales."[97]

145. Non-Party Purdue was aware of suspicious doctors and pharmacies from the information contained in prescribing records, pharmacy orders, field reports from sales representatives and, in some instances, its own surveillance operations.[98] Since 2002, Purdue maintained a confidential roster of suspected reckless prescribers known as "Region Zero." By 2013, there were more than 1,800 doctors in Region Zero, but Purdue had reported only 8% of them to authorities. The *Los Angeles Times* reported that "[a] former Purdue executive, who monitored pharmacies for criminal activity, acknowledged that even when the company had evidence pharmacies were colluding with drug dealers, it did not stop supplying distributors selling to those stores."[99]

3. Non-Party, Purdue Funded Publications and Presentations with False and Misleading Messaging

146. As explained above, Non-Party Purdue's false and deceptive marketing scheme did not end with its own sales representatives and branded marketing materials. Extending far beyond the margin of legitimate and truthful marketing, Purdue engaged third parties including doctors and front

[96] An 80 mg tablet is equivalent in strength to 16 Vicodin tablets and was generally reserved by doctors for patients with severe, chronic pain who had built up a tolerance over months or years. In the illegal drug trade, however, "80s" were the most in demand. For those attempting to detect how OxyContin was getting onto the black market, a physician writing a high volume of 80s was a red flag. Harriet Ryan, *et al.*, *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, L.A. Times (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/ (hereinafter "Ryan, *More than 1 million*").

[97] Keefe, *Empire of Pain*, *supra* n.4.

[98] Purdue's "Abuse and Diversion Detection" program requires its sales representatives to report to the company any facts that suggest a healthcare provider to whom it markets opioids may be involved in the abuse or illegal diversion of opioid products. When a provider is reported under the program, Purdue purportedly conducts an internal inquiry regarding the provider to determine whether he or she should be placed on a "no-call" list. If a provider is placed on this list, Purdue sales representatives may no longer contact the provider to promote the company's opioid products. Bill Fallon, *Purdue Pharma agrees to restrict marketing of opioids*, Stamford Advocate (Aug. 25, 2015), available at https://www.stamfordadvocate.com/business/article/Purdue-Pharma-agrees-to-restrict-marketing-of-6464800.php (hereinafter "Fallon, *Purdue Pharma agrees*").

[99] Ryan, *More than 1 Million*, *supra* n.127.

groups to spread the false message of prescription opioids' safety and efficacy.

147. Non-Party Purdue caused the publication and distribution of false and deceptive guidelines on opioid prescribing. For example, as set forth above, Purdue paid $100,000 to the FSMB to help print and distribute its guidelines on the use of opioids to treat chronic pain to ***700,000*** practicing doctors; among them FSMB's members Florida Board of Medicine and the Florida Board of Osteopathic Medicine.

148. One of the advisors for Fishman's 2007 publication "Responsible Opioid Prescribing: A Physician's Guide" and its 2012 update was Haddox, a longtime member of Purdue's speakers' bureau who later became a Purdue vice president.

149. Similarly, multiple videos feature Fine delivering educational talks about the drugs.[100] In one video from 2011, titled "Optimizing Opioid Therapy," he sets forth a "Guideline for Chronic Opioid Therapy" discussing "opioid rotation" (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it may take four or five switches over a person's "lifetime" to manage pain.[101] He states the "goal is to improve effectiveness which is different from efficacy and safety." Rather, for chronic pain patients, effectiveness "is a balance of therapeutic good and adverse events ***over the course of years***." The entire program assumes that opioids are appropriate treatment over a "protracted period of time" and even over a patient's entire "lifetime." He even suggests that opioids can be used to treat ***sleep apnea***. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with "tools," but leaves that for "a whole other lecture."[102]

150. Non-Party, Purdue provided many "teaching" materials free of charge to the Joint

[100] Weber, *Two Leaders in Pain*, *supra* n.85.
[101] Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), available at https://www.youtube.com/watch?v=_G3II9yqgXI.
[102] *Id.*

Commission.

151. Non-Party, Purdue also deceptively marketed the use of opioids for chronic pain through the APF, which was shut down after the launch of the Senate investigation in 2012. In 2010 alone, the APF received 90% of its funding from drug and medical device companies, including from Purdue. Purdue paid APF unspecified amounts in 2008 and 2009 and between $100,000 and $499,999 in 2010.[103]

4. The Guilty Pleas

152. In May 2007, Non-Party, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay $600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science. Additionally, Michael Friedman ("Friedman"), the company's president, pled guilty to a misbranding charge and agreed to pay $19 million in fines; Howard R. Udell ("Udell"), Purdue's top lawyer, also pled guilty and agreed to pay $8 million in fines; and Paul D. Goldenheim ("Goldenheim"), its former medical director, pled guilty as well and agreed to pay $7.5 million in fines.

153. In a statement announcing the guilty plea, John Brownlee ("Brownlee"), the U.S. Attorney for the Western District of Virginia, stated:

> Purdue claimed it had created the miracle drug – a low risk drug that could provide long acting pain relief but was less addictive and less subject to abuse. ***Purdue's marketing campaign worked, and sales for OxyContin skyrocketed – making billions for Purdue and millions for its top executives.***
>
> But OxyContin offered no miracles to those suffering in pain. Purdue's claims that OxyContin was less addictive and less subject to abuse and diversion

[103] American Pain Foundation Partner Report, GuideStar, available at http://www.guidestar.org/PartnerReport.aspx?ein=52-2002328&Partner=Demo (last visited Mar. 09, 2018) (links to annual reports at bottom of page).

> were false – and Purdue knew its claims were false. The result of their ***misrepresentations and crimes sparked one of our nation's greatest prescription drug failures*** . . .OxyContin was the child of marketers and bottom line financial decision-making.[104]

154. Brownlee characterized Purdue's criminal activity as follows:

> First, ***Purdue trained its sales representatives to falsely inform health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse***. Purdue ordered this training even though its own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet by simply crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe.
>
> Second, ***Purdue falsely instructed its sales representatives to inform health care providers that OxyContin could create fewer chances for addiction*** than immediate-release opioids.
>
> ***Third,*** Purdue sponsored training that falsely taught Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse ***than short-acting opioids.***
>
> Fourth, ***Purdue falsely told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance*** to the drug.
>
> And fifth, ***Purdue falsely told health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids***, and could be used to "weed out" addicts and drug seekers.[105]

155. Specifically, Non-Party, Purdue pled guilty to illegally misbranding OxyContin in an effort to mislead and defraud physicians and consumers, while Friedman, Udell and Goldenheim pled guilty to the misdemeanor charge of misbranding OxyContin for introducing misbranded drugs into interstate commerce in violation of 21 U.S.C. §§331(a), 333(a)(1)-(2) and 352(a).

---

[104] Press Release, U.S. Attorney for the Western District of Virginia, Statement of United States Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and Its Executives for Illegally Misbranding OxyContin (May 10, 2007), available at https://assets.documentcloud.org/documents/279028/purdue-guilty-plea.pdf.

[105] *Id.*

156. Nevertheless, even after the settlement, Non-Party, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund seemingly neutral organizations to disseminate the message that opioids were both effective and non-addictive. Purdue continues to aggressively market the liberal prescribing of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007,

> it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly nine hundred million dollars on lobbying and political contributions – eight times what the gun lobby spent during that period.[106]

157. Non-Party, Purdue has earned more than $31 billion from OxyContin, the nation's bestselling painkiller, which constitutes approximately 30% of the U.S. market for painkillers. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up threefold from 2006 sales of $800 million.[107]

158. Non-Party, Purdue also made thousands of payments to physicians nationwide, including payments to physicians in the geographic region served by Plaintiff, for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services.

159. OxyContin has been widely prescribed in the geographic region served by Plaintiff. According to data collected by ProPublica, during 2014 and 2015, Florida doctors' prescriptions of OxyContin to patients insured by the Medicare Part D program totaled more than $60 million and $62.3 million, respectively.

5. Non-Party Purdue Failed to Report Suspicious Sales as Required

160. The Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C §801,

[106] Keefe, *Empire of Pain*, *supra* n.4.
[107] Eban, *Painful Medicine*, *supra* n.100.

et seq. ("CSA" or "Controlled Substances Act"), and the regulations promulgated thereunder, 21 C.F.R. §1300 *et seq*., which is incorporated into Florida law by Fla. Stat. §499.0121(10) and (15)(b), imposes on all "registrants" the obligation to design and operate a system to disclose to the registrant suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R.§1301.74(b).

161. Non-Party, Purdue is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

162. Non-Party, Purdue failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Purdue's failure to timely report suspicious sales violated the CSA.

B. Janssen and J&J

163. Janssen and J&J manufactures, markets, sells, and distributes the following opioids in the geographic region served by Plaintiff and nationwide:

Duragesic (fentanyl)	Opioid analgesic delivered via skin patch; contains gel form of fentanyl, a synthetic opioid that is up to 100 times more potent than morphine; delivers fentanyl at regulated rate for up to 72 hours; first approved by the FDA in August 1990.	Schedule II
Nucynta ER (tapentadol hydrochloride)	Opioid agonist; extended-release formulation indicated for severe pain.	Schedule II
Nucynta (tapentadol hydrochloride)	Immediate-release version of tapentadol hydrochloride for the management of moderate to severe acute pain.	Schedule II

164. Janssen and J&J introduced Duragesic in 1990. It is indicated for the "management of

pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Janssen and J&J also markets Nucynta, which was first approved by the FDA in 2008, formulated in tablet form and in an oral solution and indicated for the "relief of moderate to severe acute pain in patients 18 years of age or older." Additionally, Janssen and J&J markets Nucynta ER, which was first approved by the FDA in 2011 in tablet form. Initially, it was indicated for the "management of . . . pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." This pain indication was later altered to "management of moderate to severe chronic pain in adults" and "neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults." Janssen sold Nucynta and Nucynta ER to Depomed in 2015 for $1.05 billion.

1. The FDA Warned Janssen Regarding Its False Messaging

165. On February 15, 2000, the FDA sent Janssen a letter concerning the alleged dissemination of "homemade" promotional pieces that promoted Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA explained that the "homemade" promotional pieces were "false or misleading because they contain misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance."

166. The March 30, 2000 letter identified specific violations, including misrepresentations that Duragesic had a low potential for abuse:

> - You present the claim, "Low abuse potential!" This claim suggests that Duragesic has less potential for abuse than other currently available opioids. However, this claim has not been demonstrated by substantial evidence. Furthermore, this claim is contradictory to information in the approved product labeling (PI) that states, "Fentanyl is a Schedule II controlled substance and can produce drug dependence similar to that

produced by morphine." Therefore, this claim is false or misleading.[108]

167. The March 30, 2000 letter also stated that the promotional materials represented that Duragesic was "more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence." Specifically, the FDA stated that Janssen was marketing Duragesic for indications other than the treatment of chronic pain that cannot otherwise be managed, for which it was approved:

> - You present the claim, "It's not just for end stage cancer anymore!" This claim suggests that Duragesic can be used for any type of pain management. However, the PI for Duragesic states, "Duragesic (fentanyl transdermal system) is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by lesser means…" Therefore, the suggestion that Duragesic can be used for any type of pain management promotes Duragesic[] for a much broader use than is recommended in the PI, and thus, is misleading. In addition, the suggestion that Duragesic can be used to treat any kind of pain is contradictory to the boxed warning in the PI. Specifically, the PI states,
>
> BECAUSE SERIOUS OR LIFE-THREATENING HYPOVENTILATION COULD OCCUR, DURAGESIC® (FENTANYL TRANSDERMAL SYSTEM) IS CONTRAINDICATED:
>
> - In the management of acute or post-operative pain, including use in out- patient surgeries….[109]

168. The March 30, 2000 letter also stated Janssen failed to adequately present "contraindications, warnings, precautions, and side effects with a prominence and readability reasonably comparable to the presentation of information relating to the effectiveness of the product":

> Although this piece contains numerous claims for the efficacy and safety of Duragesic, ***you have not presented any risk information*** concerning the boxed warnings, contraindications, warnings, precautions, or side effects

[108] NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutica (Mar. 30, 2000) at 2.
[109] *Id.* at 2-3.

> associated with Duragesic's use…. Therefore, this promotional piece is lacking in fair balance, or otherwise misleading, because it fails to address important risks and restrictions associated with Duragesic therapy.[110]

169. On September 2, 2004, the U.S. Department of Health and Human Services ("HHS") sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and…unsubstantiated effectiveness claims for Duragesic," including, specifically, "suggesting that Duragesic has a lower potential for abuse compared to other opioid products."

170. The September 2, 2004 letter warned Janssen regarding its claims that Duragesic had a low reported rate of mentions in the Drug Abuse Warning Network ("DAWN") as compared to other opioids. The letter stated that the claim was false or misleading because the claim was not based on substantial data and because the lower rate of mentions was likely attributable to Duragesic's lower frequency of use compared to other opioids listed in DAWN:

> The file card presents the prominent claim, "Low reported rate of mentions in DAWN data," along with Drug Abuse Warning Network (DAWN) data comparing the number of mentions for Fentanyl/combinations (710 mentions) to other listed opioid products, including Hydrocodone/combinations (21,567 mentions), Oxycodone/combinations (18,409 mentions), and Methadone (10,725 mentions). The file card thus suggests that Duragesic is less abused than other opioid drugs.
>
> This is false or misleading for two reasons. First, we are not aware of substantial evidence or substantial clinical experience to support this comparative claim. The DAWN data cannot provide the basis for a valid comparison among these products. As you know, DAWN is not a clinical trial database. Instead, it is a national public health surveillance system that monitors drug-related emergency department visits and deaths. If you have other data demonstrating that Duragesic is less abused, please submit them.
>
> Second, Duragesic is not as widely prescribed as other opioid products. As a result, the relatively lower number of mentions could be attributed to the lower frequency of use, and not to a lower incidence of abuse. The file card

[110] *Id.* at 3. (emphasis in original).

fails to disclose this information.[111]

171. The September 2, 2004 letter also detailed a series of unsubstantiated false or misleading claims regarding Duragesic's effectiveness. The letter concluded that various claims made by Janssen were insufficiently supported, including that:

- "'Demonstrated effectiveness in chronic back pain with additional patient benefits, …86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep.'"
- "'All patients who experienced overall benefit from DURAGESIC would recommend it to others which chronic low back pain.'"
- "'Significantly reduced nighttime awakenings.'"
- "'Significant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index.'"
- "'Significant improvement in physical functioning summary scores.'"
- "'Significant improvement in social functioning.'"[112]

172. In addition, the September 2, 2004 letter identified "outcome claims [that] are misleading because they imply that patients will experience improved social or physical functioning or improved work productivity when using Duragesic." The claims include "'1,360 loaves[[sic]...and counting,' '[w]ork, uninterrupted,' '[l]ife, uninterrupted,' '[g]ame, uninterrupted,' '[c]hronic pain relief that supports functionality,' '[h]elps patients think less about their pain,' and '[i]mprove[s]…physical and social functioning.'" The September 2, 2004 letter stated: "Janssen has not provided references to support these outcome claims. We are not aware of substantial evidence or substantial clinical experience to support these claims."[113]

---

[111] Warning Letter from Thomas W. Abrams, U.S. Department of Health and Human Services, to Ajit Shetty, Janssen Pharmaceutica, Inc. (Sept. 2, 2004), available at http://www.johnsonandtoxin.com/040920_duragesic_letter.pdf, at 2.
[112] *Id.* at 2-3.
[113] *Id.* at 3.

173. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been "'examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch'" and noted the possibility "that patients and physicians might be unaware of the risks" of using the fentanyl transdermal patch, which is a potent opioid analgesic meant to treat chronic pain that does not respond to other painkillers.

2. Janssen and J&J Funded False Publications and Presentations

174. Despite these repeated warnings, Janssen and J&J continued to falsely market the risks of opioids. In 2009, PriCara, a "Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.," sponsored a 2009 brochure, titled "Finding Relief: Pain Management for Older Adults," aimed at potential patients. The brochure included a free DVD featuring actress Kathy Baker, who played a doctor in the popular television series "Picket Fences."

175. The brochure represented that it was a source for older adults to gain accurate information about treatment options for effective pain relief:

> This program is aimed specifically at older adults and what they need to know to get effective pain relief. You will learn that there are many pathways to this relief.
>
> You will learn about your options for pain management and how to find the treatment that's right for you. By learning more about pain and the many ways it can be treated, you are taking solid steps toward reducing the pain you or a loved one may be feeling.[114]

176. Despite representing itself as a source of accurate information, the brochure included false and misleading information about opioids, including a section seeking to dispel purported "myths" about opioid usage:

[114] *Finding Relief, Pain Management for Older Adults* (2009).

> **Opioid Myths**
>
> **Myth:** Opioid medications are always addictive.
>
> **Fact:** Many studies show that opioids are ***rarely*** addictive when used properly for the management of chronic pain.
>
> **Myth:** Opioids make it harder to function normally.
>
> **Fact:** When used correctly for appropriate conditions, opioids may make it ***easier*** for people to live normally.
>
> **Myth:** Opioid doses have to get bigger over time because the body gets used to them.
>
> **Fact:** Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.[115]

177. Among the "Partners" listed in "Finding Relief: Pain Management for Older Adults" are the AAPM, the American Geriatrics Society ("AGS") and the AGS Foundation for Health in Aging. Janssen (along with Purdue and Endo) funded the AAPM. The AGS and the AGS Foundation for Health in Aging published a pain guide titled "Finding Relief: Pain Management for Older Adults," which was funded by Janssen.[116]

178. In addition, Janssen and J&J disseminated false information about opioids on the website Prescribe Responsibly, which remains publicly accessible at www.prescriberesponsibly.com. According to the website's legal notice, all content on the site "is owned or controlled by Janssen."[117] The website includes numerous false or misleading representations concerning the relative safety of opioids and omissions of the risks associated with taking them. For example, it states that while practitioners are often concerned about prescribing opioids due to "questions of addiction," such concerns "are often overestimated. According to clinical opinion polls, true addiction occurs only in

[115] *Id.* (emphasis in original).
[116] *Id.*
[117] *Legal Notice*, Prescribe Responsibly, http://www.prescriberesponsibly.com/legal-notice (last visited Mar. 09, 2018).

a small percentage of patients with chronic pain who receive chronic opioid analgesic[]…therapy."[118]

179. Prescribe Responsibly also compared the risks of opioid use favorably to those associated with nonsteroidal anti-inflammatory drugs ("NSAIDs"), such as aspirin and ibuprofen, and stated that many patients develop tolerance for opioid side effects:

> Opioid analgesics are often the first line of treatment for many painful conditions and may offer advantages over nonsteroidal anti-inflammatory drugs (NSAIDs). Opioid analgesics, for example, have no true 'ceiling dose' for analgesia and do not cause direct organ damage; however, they do have several possible side effects, including constipation, nausea, vomiting, a decrease in sexual interest, drowsiness, and respiratory depression. With the exception of constipation, many patients often develop tolerance to most of the opioid analgesic-related side effects.[119]

180. Further, Prescribe Responsibly repeats the scientifically unsupported discussion of "pseudo addiction" as "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately, the inappropriate behavior ceases."[120] Thus, pseudo addiction is defined as a condition requiring the prescription of more or stronger opioids.

181. Janssen also made thousands of payments to physicians nationwide, including payments to physicians in the geographic region served by Plaintiff, for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services.

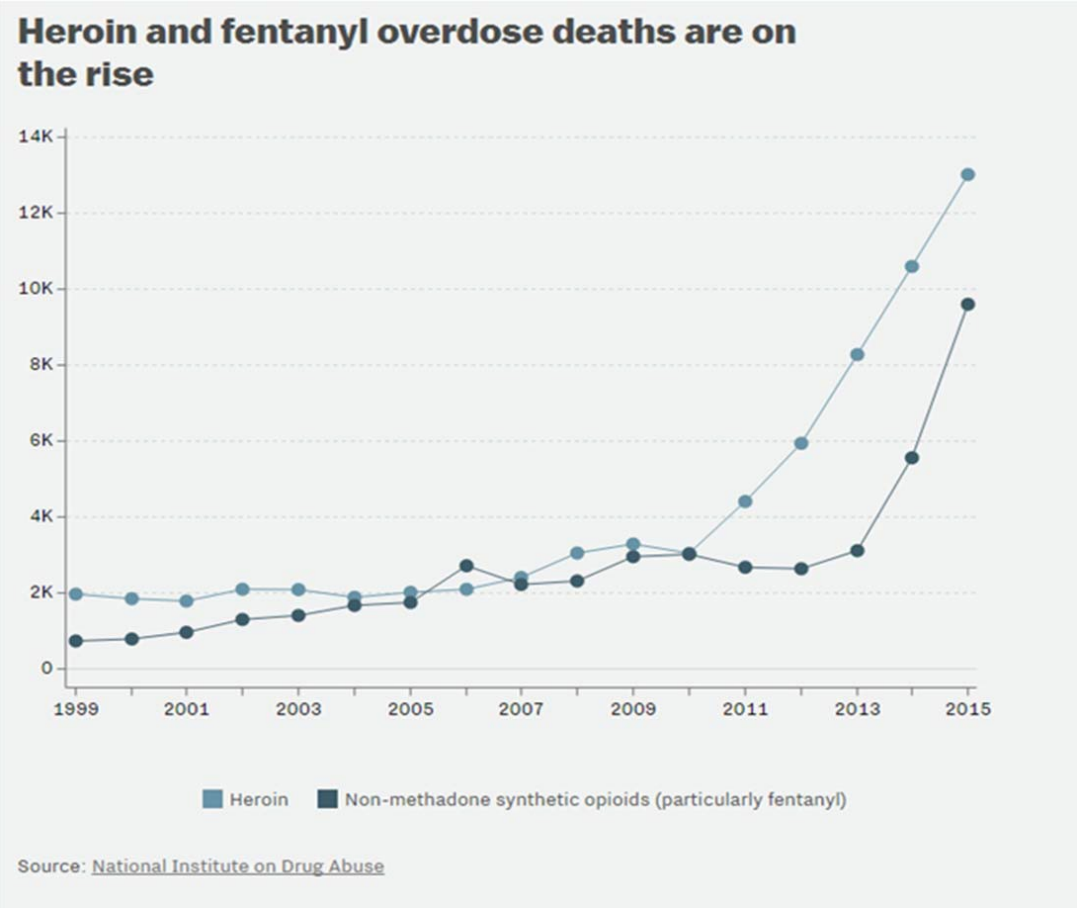
182. According to data collected by *ProPublica*, in 2014, Florida doctors prescribed more than $2 million worth of Duragesic, nearly $2 million worth of Nucynta, and approximately $2.2 million worth of Nucynta ER to patients insured by Medicare Part D. In 2015, Medicare part D

---

[118] *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, available at http://www.prescriberesponsibly.com/articles/opioid-pain-management (last visited Mar. 09, 2018).
[119] *Id.*
[120] *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, available at http://www.prescriberesponsibly.com/articles/before-prescribing-opioids (last visited Mar 14, 2018).

prescriptions totaled more than $2.1 million worth of Duragesic, almost $2.6 million worth of Nucynta and more than $3.5 million of Nucynta ER.

183. As people became increasingly hooked on prescription pain killers, they moved to heroin, and in turn increasingly to fentanyl, which is even more potent and cheaper than heroin, and which, as set forth above, was being deceptively marketed by Janssen and J&J, causing a dramatic spike in heroin and fentanyl overdose deaths:



3. Janssen Failed to Report Suspicious Sales as Required

184. The federal CSA imposes on all "registrants" the obligation to design and operate a system to disclose to the registrant suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and

orders of unusual frequency." 21 C.F.R. §1301.74(b).

185. Janssen is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

186. Janssen failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Janssen's failure to timely report suspicious sales violated the CSA.

C. Endo

187. Endo manufactures, markets, sells and distributes the following opioids in the geographic region served by Plaintiff and nationwide:

Opana ER (oxymorphone hydrochloride)	Opioid agonist; extended-release tablet formulation; first drug in which oxymorphone is available in an oral, extended-release formulation; first approved in 2006.	Schedule II
Opana (oxymorphone hydrochloride)	Opioid agonist; first approved in 2006.	Schedule II
Percodan (oxymorphone hydrochloride and aspirin)	Branded tablet combining oxymorphone hydrochloride and aspirin; first approved in 1950; first marketed by Endo in 2004.	Schedule II
Percocet (oxymorphone hydrochloride and acetaminophen)	Branded tablet that combines oxymorphone hydrochloride and acetaminophen; first approved in 1999; first marketed by Endo in 2006.	Schedule II
Oxycodone	Generic product.	Schedule II
Oxymorphone	Generic product.	Schedule II
Hydromorphone	Generic product.	Schedule II
Hydrocodone	Generic product.	Schedule II

188. The FDA first approved an injectable form of Opana in 1959. The injectable form of Opana was indicated "for the relief of moderate to severe pain" and "for preoperative medication, for support of anesthesia, for obstetrical analgesia, and for relief of anxiety in patients with dyspnea

associated with pulmonary edema secondary to acute left ventricular dysfunction." However, oxymorphone drugs were removed from the market in the 1970s due to widespread abuse.[121]

189. In 2006, the FDA approved a tablet form of Opana in 5 mg and 10 mg strengths. The tablet form was "indicated for the relief of moderate to severe acute pain where the use of an opioid is appropriate." Also in 2006, the FDA approved Opana ER, an extended-release tablet version of Opana available in 5 mg, 10 mg, 20 mg and 40 mg tablet strengths. Opana ER was indicated "for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time." Endo's goal was to use Opana ER to take market share away from OxyContin; it was thus marketed as being safer, and with less abuse potential than OxyContin because of its crush-resistance.

190. According to Endo's annual reports, sales of Opana and Opana ER regularly generate several hundred million dollars in annual revenue for the company, growing from $107 million in 2007 to as high as $384 million in 2011. Over the last ten years, Percocet has generated an average of well over $100 million in annual revenue for the company.

1. Endo Falsely Marketed Opana ER as Crush Resistant

191. In December 2011, the FDA approved a reformulated version of Opana ER, which Endo claimed offered "safety advantages" over the original formulation because the latter "'is resistant to crushing by common methods and tools employed by abusers of prescription opioids . . . [and] is less likely to be chewed or crushed even in situations where there is no intent for abuse, such as where patients inadvertently chew the tablets, or where caregivers attempt to crush the tablets for easier administration with food or by gastric tubes, or where children accidentally gain access to the

[121] John Fauber & Kristina Fiore, *Opana gets FDA approval despite history of abuse, limited effectiveness in trials*, Milwaukee Journal Sentinel (May 9, 2015), available at http://archive.jsonline.com/watchdog/watchdogreports/opana-gets-fda-approval-despite-history-of-%20abuse-limited-effectiveness-in-trials-b99494132z1-303198321.html/.

tablets.'"[122]

192. Endo publicized the reformulated version of Opana ER as "crush-resistant." To combat the fear of opioids, sales representatives touted it to doctors as a safer option owing to its crush-resistance and extended release. In a December 12, 2011 press release announcing FDA approval of the reformulated Opana ER, Endo's executive vice president for research and development and chief scientific officer highlighted the reformulated version's safety characteristics:

> FDA's approval of this new formulation of Opana ER is an important milestone for both the Long Acting Opioid category as well as Endo's branded pharmaceutical portfolio. . . . Patient safety is our top concern and addressing appropriate use of opioids is a responsibility that we take very seriously. We firmly believe this new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefitpatients, physicians and payers.[123]

193. However, in October 2012, the CDC issued a health alert noting that 15 people in Tennessee had contracted thrombotic thrombocytopenic purpura, a rare blood-clotting disorder, after injecting reformulated Opana ER. In response, Endo's chief scientific officer stated that, while Endo was looking into the data, he was not especially concerned: "'Clearly, we are looking into this data, . . .but it's in a very, very distinct area of the country.'"[124]

194. Shortly thereafter, the FDA determined that Endo's conclusions about the purported safety advantages of the reformulated Opana ER were unfounded. In a May 10, 2013 letter to Endo, the FDA found that the tablet was still vulnerable to "'cutting, grinding, or chewing,'" "'can be

---

[122] FDA-2012-P-0895 Letter from Janet Woodcock, M.D., Center for Drug Evaluation and Research, to Richard Barto, Endo Pharmaceuticals, available at https://www.pharmamedtechbi.com/~/media/Supporting%20Documents/The%20Pink%20Sheet%20DAILY/2013/May/FDA_CDER_Final_RespEndo_Pharmaceuticals_Inc_Petition_Denial.pdf at 4. (hereafter "Letter from Janet Woodcock").

[123] Press Release, Endo Announces FDA Approval of New Formulation of Opana ER Designed to be Crush-Resistant (Dec. 12, 2011), available at https://www.prnewswire.com/news-releases/endo-announces-fda-approval-of-a-new-formulation-of-opana-er-designed-to-be-crush-resistant-135431073.html.

[124] Jake Harper & Kelly McEvers, *How A Painkiller Designed To Deter Abuse Helped Spark An HIV Outbreak*, National Public Radio (Apr. 1, 2016), available at https://www.npr.org/sections/health-shots/2016/04/01/472538272/how-a-painkiller-designed-to-deter-abuse-helped-spark-an-hiv-outbreak.

prepared for insufflation (snorting) using commonly available tools and methods,'" and "'can [be readily] prepared for injection.'" It also warned that preliminary data suggested "the troubling possibility that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation."[125]

195. A 2014 study co-authored by an Endo medical director corroborated the FDA's warning. This 2014 study found that while overall abuse of Opana had fallen following Opana ER's reformulation, it also found that injection had become the preferred way of abusing the drug.[126] However, the study reassured that it was not possible to draw a causal link between the reformulation and injection abuse.

196. The study's failure to adequately warn healthcare providers and the public was catastrophic. On April 24, 2015, the CDC issued a health advisory concerning its investigation of "a large outbreak of recent human immunodeficiency virus (HIV) infections among persons who inject drugs."[127] The CDC specifically attributed the outbreak to the injection of Opana ER. As the advisory explained:

> From November 2014 to January 2015, ISDH identified 11 new HIV infections in a rural southeastern county where fewer than 5 infections have been identified annually in the past. As of April 21, 2015, an on-going investigation by ISDH with assistance from CDC has identified 135 persons with newly diagnosed HIV infections in a community of 4,200 people; 84% were also HCV infected. Among 112 persons interviewed thus far, 108 (96%) injected drugs; all reported dissolving and injecting tablets of the prescription-type opioid oxymorphone (OPANA® ER) using shared drug preparation and injection equipment.[128]

[125] Letter from Janet Woodcock, *supra* n. 153 at 2 n.5.
[126] Harper, *supra* n. 155.
[127] *Outbreak of Recent HIV and HCV Infections Among Persons Who Inject Drugs*, Centers for Disease Control and Prevention, https://stacks.cdc.gov/view/cdc/30591 (last visited Mar. 14, 2018).
[128] *Id.*

2. New York's Investigation Found Endo Falsely Marketed Opana ER

197. On February 18, 2017, the State of New York announced a settlement with Endo requiring it "to cease all misrepresentations regarding the properties of Opana ER [and] to describe accurately the risk of addiction to Opana ER."[129] In the Assurance of Discontinuance that effectuated the settlement, the State of New York revealed evidence showing that Endo had known about the risks arising from the reformulated Opana ER even before it received FDA approval.

198. Among other things, the investigation concluded that:

- ***Endo improperly marketed Opana ER as designed to be crush resistant, when Endo's own studies dating from 2009 and 2010 showed that the pill could be crushed and ground;***
- ***Endo improperly instructed its sales representatives to diminish and distort the risks associated with Opana ER, including the serious danger of addiction; and***
- ***Endo made unsupported claims comparing Opana ER to other opioids and failed to disclose accurate information regarding studies addressing the negative effects of Opana ER.***

199. In October 2011, Endo's director of project management e-mailed the company that had developed the formulation technology for reformulated Opana ER to say there was little or no difference between the new formulation and the earlier formulation, which Endo withdrew due to risks associated with grinding and chewing:

> "***We already demonstrated that there was little difference between [the original and new formulations of Opana] in Study 108 when both products were ground. FDA deemed that there was no difference*** and this contributed to their statement that we had not shown an incremental benefit. ***The chewing study (109) showed the same thing no real difference*** which the FDA used

[129] Press Release, Attorney General Eric T. Schneiderman, A.G. Schneiderman Announces Settlement With Endo Health Solutions Inc. & Endo Pharmaceuticals Inc. Over Marketing Of Prescription Opioid Drugs (Mar. 3, 2016), https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals.

to claim no incremental benefit."[130]

200. Endo conducted two additional studies to test the reformulated Opana ER's crush resistance. Study 901 tested whether it was more difficult to extract reformulated Opana ER than the original version, and whether it would take longer to extract from reformulated Opana ER than from the original version. The test revealed that both formulations behaved similarly with respect to manipulation time and produced equivalent opioid yields.

201. The settlement also identified and discussed a February 2013 communication from a consultant hired by Endo to the company, in which the consultant concluded that "'[t]he initial data presented do not necessarily establish that the reformulated Opana ER is tamper resistant.'" The same consultant also reported that the distribution of the reformulated Opana ER had already led to higher levels of abuse of the drug via injection.[131]

202. Regardless, pamphlets produced by Endo and distributed to physicians misleadingly marketed the reformulated Opana ER as "'designed to be' crush resistant," and Endo's sales representative training identified Opana ER as "CR," short for crush resistant.[132]

203. The Office of the Attorney General of New York also revealed that the "managed care dossier" Endo provided to formulary committees of healthcare plans and pharmacy benefit managers misrepresented the studies that had been conducted on Opana ER. The dossier was distributed in order to assure the inclusion of reformulated Opana ER in their formularies.

204. According to Endo's vice president for pharmacovigilance and risk management, the dossier was presented as a complete compendium of all research on the drug. However, it omitted

[130] *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No. 15-228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 5 (Mar. 1, 2016), https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.
[131] *Id.* at 6.
[132] *Id.*

certain studies: Study 108 (completed in 2009) and Study 109 (completed in 2010), which showed that reformulated Opana ER could be ground and chewed.

205. The settlement also detailed Endo's false and misleading representations about the non-addictiveness of opioids and Opana. Until April 2012, Endo's website for the drug, www.opana.com, contained the following representation: "'Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.'"[133] However, Endo neither conducted nor possessed a survey demonstrating that most healthcare providers who treat patients with pain agree with that representation.

206. The Office of the Attorney General of New York also disclosed that training materials provided by Endo to sales representatives stated: "'Symptoms of withdrawal do not indicate addiction.'"[134] This representation is inconsistent with the diagnosis of opioid-use disorder as provided in the Diagnostic and Statistical Manual of Mental Disorders by the American Psychiatric Association (Fifth Edition).

207. The Office of the Attorney General of New York also found that Endo trained its sales representatives to falsely distinguish addiction from "pseudo addiction," which it defined as a condition in which patients exhibit drug-seeking behavior that resembles but is not the same as addiction. However, Endo's vice president for pharmacovigilance and risk management testified that he was not aware of any research validating the concept of pseudo addiction.

208. On June 9, 2017, the FDA asked Endo to voluntarily cease sales of Opana ER after determining that the risks associated with its abuse outweighed the benefits. According to Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, the risks include "several serious problems," including "outbreaks of HIV and Hepatitis C from sharing the drug after it

[133] *Id.*
[134] *Id.* at 7.

was extracted by abusers" and "a[n] outbreak of serious blood disorder." If Endo does not comply with the request, Dr. Woodcock stated that the FDA would issue notice of a hearing and commence proceedings to compel its removal.

3. Endo Funded False Publications and Presentations

209. Like several of the other Manufacturing Defendants, Endo provided substantial funding to purportedly neutral medical organizations, including the APF.

210. For example, in April 2007, Endo sponsored an article aimed at prescribers, written by Dr. Charles E. Argoff in *Pain Medicine News*, titled "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain."[135]

211. The article commenced with the observation that "[a]n estimated 50 to 60 million people . . . suffer from chronic pain." It continued:

> Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.[136]

212. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids. It concluded by saying that the "use of opioids may be effective in the management of chronic pain."

213. Later, in 2014, Endo issued a patient brochure titled "Understanding Your Pain:

[135] Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, https://www.painmedicinenews.com/download/BtoB_Opana_WM.pdf.
[136] *Id.*

Taking Oral Opioid Analgesics." It was written by nurses Margo McCaffery and Chris Pasero and edited by APF board member Portenoy.

214. The brochure included numerous false and misleading statements minimizing the dangers associated with prescription opioid use. Among other things, the brochure falsely and misleadingly represented that:

> Addiction **IS NOT** when a person develops "withdrawal" (such as abdominal cramping or sweating) after the medicine is stopped quickly or the dose is reduced by a large amount. Your doctor will avoid stopping your medication suddenly by slowly reducing the amount of opioid you take before the medicine is completely stopped. Addiction also **IS NOT** what happens when some people taking opioids need to take a higher dose after a period of time in order for it to continue to relieve their pain. This normal "tolerance" to opioid medications doesn't affect everyone who takes them and does not, by itself, imply addiction. If tolerance does occur, it does not mean you will "run out" of pain relief. Your dose can be adjusted or another medicine can be prescribed.
>
> * * *
>
> *How can I be sure I'm not addicted?*
>
> Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problems.
>
> - Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons – to relieve your pain and improve your function. You are not addicted.
>
> * * *
>
> Your doctor or nurse may instruct you to do some of the following:
>
> - Take the next dose before the last dose wears off. If pain is present most of the day and night, the pain medicine may be taken at regularly scheduled times. If you are taking a short-acting opioid, this usually means taking it every 4 hours. You may need to set your alarm, especially at night, to be sure you take your dose before the pain returns and wakes you up.
>
> - If your pain comes and goes, take your pain medicine when pain first begins, before it becomes severe.
>
> - If you are taking a long-acting opioid, you may only need to take it every

> 8 to 12 hours, but you may also need to take a short-acting opioid in between for any increase in pain.[137]

215. In 2008, Endo also provided an "educational grant" to PainEDU.org, which produced a document titled "Screener and Opioid Assessment for Patients with Pain (SOAPP) Version 1.0-14Q." Endo and King Pharmaceuticals sponsor PainEDU.org.[138] SOAPP describes itself "as a tool for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require." It falsely highlights purportedly "recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems."

216. Endo also sponsored the now-defunct website painknowledge.com, which was created by the APF and stated it was "a one-stop repository for print materials, educational resources, and physician tools across the broad spectrum of pain assessment, treatment, and management approaches."[139] Among other featured content, painknowledge.com included a flyer titled "Pain: Opioid Therapy," which failed to warn of significant adverse effects that could arise from opioid use, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, decreased tolerance, dependence and addiction.

217. Endo, along with Janssen and Purdue, also provided grants to APF to distribute Exit Wounds, discussed above. *See supra* ¶69.[140]

---

[137] Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharmaceuticals (2004), http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf (emphasis in original).

[138] B. Eliot Cole, *Resources for Education on Pain and Its Management: A Practitioner's Compendium* 2 (Am. Society of Pain Educators 2009), https://www.paineducators.org/wp-content/uploads/2012/12/ASPE-ResForEducationOnPainAn.pdf.

[139] *AboutPainKnowledge.org*, PainKnowledge, available at http://web.archive.org/web/20120120094923/http://www.painknowledge.org/aboutpaink.aspx (last visited Mar. 14, 2018).

[140] *Iraq War Veteran Amputee, Pain Advocate and New Author Release Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families*, Coalition for Iraq + Afghanistan Veterans, available at https://web.archive.org/web/20160804131030/http://coalitionforveterans.org/2009/10/iraq-war-veteran-amputee-pain-advocate-and-new-author-releases-exit-wounds-a-survival-guide-to-pain-management-for-returning-veterans-and-their-families/ (last visited Mar. 14, 2018).

218. Endo also made thousands of payments to physicians nationwide, including payments to physicians in the geographic region served by Plaintiff, for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services.

4. The FDA Requested Endo Withdraw Opana ER Due to the Public Health Consequences of Abuse

219. On June 8, 2017, the FDA requested that Endo remove reformulated Opana ER from the market "based on its concern that the benefits of the drug may no longer outweigh its risks."[141] According to the FDA's press release, it sought removal "due to the public health consequences of abuse." The decision to seek Opana ER's removal from sale followed a March 2017 FDA advisory committee meeting, during which a group of independent experts voted 18-8 that the drug's benefits no longer outweigh the risks associated with its use. Should Endo choose not to remove Opana ER due to the FDA's request, the agency stated that it will take steps to formally require its removal by withdrawing approval.

220. Opana ER has been widely prescribed in the geographic region served by Plaintiff. According to data collected by *ProPublica*, during 2014 and 2015, Florida doctors' prescriptions of Opana ER to patients insured by the Medicare Part D program totaled approximately $12.8 million and more than $14.8 million, respectively.

5. Endo Failed to Report Suspicious Sales as Required

221. The federal CSA imposes on all "registrants" the obligation to design and operate a system to disclose to the registrant suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious

[141] Press Release, U.S. Food & Drug Administration, FDA requests removal of Opana ER for risks related to abuse (June 8, 2017), available at https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm562401.htm.

orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

222. Endo is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

223. Endo failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Endo's failure to timely report suspicious sales violated the CSA.

D. Cephalon

224. Cephalon manufactures, markets, sells and distributes the following opioids in the geographic region served by Plaintiff and nationwide:

Actiq (fentanyl citrate)	Opioid analgesic; oral transmucosal lozenge; indicated only for the management of breakthrough pain (or "BTP") in cancer patients – pain that for a short time "breaks through" medication that otherwise effectively controls a patient's persistent pain – in patients 16 and older with malignancies; commonly referred to as a lollipop because designed to look and perform like one; approved in 1998 with restricted distribution program.	Schedule II
Fentora (fentanyl buccal)	Rapid-release tablet for BTP in cancer patients who are already receiving and tolerant of around-the-clock opioid therapy; approved 2006.	Schedule II
Generic of OxyContin (oxycodone hydrochloride)	Opiate agonist.	Schedule II

225. Actiq is designed to resemble a lollipop and is meant to be sucked on at the onset of intense BTP in cancer patients. It delivers fentanyl citrate, a powerful opioid agonist that is 80 times

stronger than morphine,[142] rapidly into a patient's bloodstream through the oral membranes.[143] Because it is absorbed through those membranes, it passes directly into circulation without having to go through the liver or stomach, thereby providing faster relief.[144]

226. In November 1998, the FDA approved Actiq for only a very narrow group of people cancer patients "with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[145]

227. Understanding the risks of introducing such an intense opioid analgesic to the market, the FDA provided approval of Actiq "***ONLY*** for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[146] Further, the FDA explicitly stated that Actiq "***must not*** be used in opioid non-tolerant patients," was contraindicated for the management of acute or postoperative pain, could be deadly to children, and was "intended to be used only in the care of opioid-tolerant cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain."

228. The FDA also required that Actiq be provided only in compliance with a strict risk-management program that explicitly limited the drug's direct marketing to the approved target

---

[142] *See* John Carreyrou, *Narcotic "Lollipop" Becomes Big Seller Despite FDA Curbs*, Wall St. J. (Nov. 3, 2006), available at https://www.opiates.com/narcotic-lollipop-becomes-big-seller-despite-fda-curbs/ (hereinafter "Carreyrou, *Narcotic Lollipop*").

[143] Actiq would later become part of a category of opioids now known as transmucosal immediate- release fentanyl ("TIRF") products. "Transmucosal" refers to the means through which the opioid is delivered into a patient's bloodstream, across mucous membranes, such as inside the cheek, under the tongue or in the nose.

[144] *Cephalon, Inc.*, Company-Histories.com, available at http://www.company-histories.com/Cephalon-Inc-Company-History.html (last visited Mar. 14, 2018).

[145] 1998 FDA Label.

[146] NDA 20-747 Letter from Cynthia McCormick, Center for Drug Evaluation and Research, to Patricia J. Richards, Anesta Corporation, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20747ltr.pdf.

audiences, defined as oncologists, pain specialists, their nurses and office staff.[147]

229. In October 2000, Cephalon acquired the worldwide product rights to Actiq and began marketing and selling Actiq in the United States.

230. Cephalon purchased the rights to Fentora, an even faster-acting tablet formulation of fentanyl, from Cima Labs, and submitted a new drug application to the FDA in August 2005. In September 2006, Cephalon received FDA approval to sell this faster-acting version of Actiq; but once again, concerned about the power and risks inherent to fentanyl, the FDA limited Fentora's approval to the treatment of BTP in cancer patients who were already tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Cephalon began marketing and selling Fentora in October 2006.

1. Cephalon Falsely and Aggressively Marketed Cancer Drug Actiq to Non-Cancer Treating Physicians

231. Due to the FDA's restrictions, Actiq's consumer base was limited, as was its potential for growing revenue. In order to increase its revenue and market share, Cephalon needed to find a broader audience and thus began marketing its lollipop to treat headaches, back pain, sports injuries and other chronic non-cancer pain, targeting non-oncology practices, including, but not limited to, pain doctors, general practitioners, migraine clinics, anesthesiologists and sports clinics. It did so in violation of applicable regulations prohibiting the marketing of medications for off-label use and in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

232. According to "data gathered from a network of doctors by research firm ImpactRx between June 2005 and October 2006" ("ImpactRx Survey"), Cephalon sales representatives' visits to non-oncologists to pitch Actiq increased six-fold between 2002 and 2005. Cephalon representatives

[147] Carreyrou, *Narcotic Lollipop*, *supra* n.173.

would reportedly visit non-oncologists monthly, providing up to 60 or 70 coupons (each coupon was good for six free Actiq lozenges) and encouraging prescribers to try Actiq on their non-cancer patients.[148]

233. Cephalon's efforts paid off. In 2000, Actiq generated $15 million in sales.[149] By 2002, it attributed a 92% increase in Actiq sales to "a dedicated sales force for ACTIQ" and "ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists."[150] By 2005, Actiq's sales total had jumped to $412 million, making it (a drug approved for only a narrow customer base) Cephalon's second-best selling drug. By the end of 2006, Actiq's sales had exceeded $500 million.[151]

234. Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. Results of the ImpactRx Survey suggested that "more than 80 percent of patients who use[d] the drug don't have cancer."[152]

2. Governmental Investigations Found Cephalon Falsely Marketed Actiq for Off-Label Uses.

235. Beginning in or about 2003, former Cephalon employees filed four whistleblower lawsuits claiming the company had wrongfully marketed Actiq for unapproved off-label uses. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay $425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Cephalon trained sales representatives to disregard restrictions of the FDA-approved

[148] *Id.*
[149] *Id.*
[150] Cephalon, Inc. Annual Report (Form 10-K) (Mar. 31, 2003), available at https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm at 28.
[151] Carreyrou, *Narcotic Lollipop*, *supra* n.173.
[152] *Id.*

label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs, and funded CME to promote off-label uses. Specifically, the DOJ stated:

> From 2001 through at least 2006, ***Cephalon was allegedly promoting [Actiq] for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy. Cephalon also promoted Actiq for use in patients who were not yet opioid-tolerant, and for whom it could have life-threatening results.***[153]

236. Then-acting U.S. Attorney Laurie Magid commented on the dangers of Cephalon's unlawful practices:

> ***This company subverted the very process put in place to protect the public from harm, and put patients' health at risk for nothing more than boosting its bottom line***. People have an absolute right to their doctors' best medical judgment. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved.[154]

237. Upon information and belief, documents uncovered in the government's investigations confirm that Cephalon directly targeted non-oncology practices and pushed its sales representatives to market Actiq for off-label use. For instance, the government's investigations confirmed:

- Cephalon instructed its sales representatives to ask non-cancer doctors whether they have the potential to treat cancer pain. Even if the doctor answered "no," a decision tree provided by Cephalon instructed the sales representatives to give these physicians free Actiq coupons;
- Cephalon targeted neurologists in order to encourage them to prescribe Actiq to patients with migraine headaches;
- Cephalon sales representatives utilized the assistance of outside pain management specialists when visiting non-cancer physicians to pitch Actiq. The pain management specialist would falsely inform the physician that Actiq does not cause patients to experience a "high" and carries a low risk of diversion toward

[153] Press Release, U.S. Department of Justice, Pharmaceutical Company Cephalon To Pay $425 Million For Off-Label Drug Marketing (Sept. 29, 2008), available at https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonrelease.pdf.
[154] *Id.*

recreational use;

- Cephalon set sales quotas for its sales and marketing representatives that could not possibly have been met solely by promoting Actiq for its FDA-approved indication;

- Cephalon promoted the use of higher doses of Actiq than patients required by encouraging prescriptions of the drug to include larger-than-necessary numbers of lozenges with unnecessarily high doses of fentanyl; and

- Cephalon promoted Actiq for off-label use by funding and controlling CME seminars that promoted and misrepresented the efficacy of the drug for off-label uses such as treating migraine headaches and for patients not already opioid-tolerant.[155]

238. Still, the letters, the FDA's safety alert, the DOJ and state investigations and the massive settlement seemed to have had little impact on Cephalon as it continued its deceptive marketing strategy for both Actiq and Fentora.

3. Cephalon Falsely and Aggressively Marketed Cancer Drug Fentora to Non-Cancer Treating Physicians

239. From the time it first introduced Fentora to the market in October 2006, Cephalon targeted non-cancer doctors, falsely represented Fentora as a safe, effective off-label treatment for non-cancer pain and continued its disinformation campaign about the safety and non-addictiveness of Fentora specifically and opioids generally. In fact, Cephalon targeted the same pain specialists and non-oncologists that it had targeted with its off-label marketing of Actiq, simply substituting Fentora.

240. During an investor earnings call shortly after Fentora's launch, Cephalon's chief executive officer described the "opportunity" presented by the use of Fentora for non-cancer pain:

[155] John Carreyrou, *Cephalon Used Improper Tactics to Sell Drug, Probe Finds*, Wall St. J., Nov. 21, 2006, https://www.wsj.com/articles/SB116407880059829145, at B1 (hereinafter "Carreyrou, *Cephalon Used Improper Tactics*").

> ***The other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower back pain and breakthrough neuropathic pain***.
>
> * * *
>
> Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%.
>
> We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and well being and the exciting growth potential that it has for Cephalon.
>
> In summary, we have had a strong launch of FENTORA and continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last seven years. In the future, with new and broader indications and a much bigger field force presence, the opportunity that FENTORA represents is enormous.[156]

4. The FDA Warned Cephalon Regarding its False and Off-Label Marketing of Fentora

241. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: "Fentora should not be used to treat any type of short-term pain."[157]

242. Nevertheless, in 2008, Cephalon pushed forward to expand the target base for Fentora and filed a supplemental drug application requesting FDA approval of Fentora for the treatment of non-cancer BTP. In the application and supporting presentations to the FDA, Cephalon admitted

[156] Seeking Alpha, Transcript of Q1 2007 Cephalon, Inc. Earnings Conference Call, May 1, 2007, https://seekingalpha.com/article/34163-cephalon-q1-2007-earnings-call-transcript at 6-7.

[157] Press Release, U.S. Food & Drug Administration, Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets) (Sept. 26, 2007), available at https://wayback.archive-it.org/7993/20170112032918/http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm.

both that it knew the drug was heavily prescribed for off-label use and that the drug's safety for such use had never been clinically evaluated.[158] An FDA advisory committee lamented that Fentora's existing risk management program was ineffective and stated that Cephalon would have to institute a risk evaluation and mitigation strategy for the drug before the FDA would consider broader label indications. In response, Cephalon revised Fentora's label and medication guide to add strengthened warnings.

243. But in 2009, the FDA once again informed Cephalon that the risk management program was not sufficient to ensure the safe use of Fentora for already approved indications.

244. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case." Rather, Fentora was only indicated for those who were already opioid tolerant. It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

245. Flagrantly disregarding the FDA's refusal to approve Fentora for non-cancer BTP and its warning against marketing the drug for the same, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq.

246. For example, on January 13, 2012, Cephalon published an insert in *Pharmacy Times* titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl

[158] *FENTORA (fentanyl buccal tablet) CII, Joint Meeting of Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisory Committee*, U.S. Food & Drug Administration (May 6, https://wayback.archive-it.org/7993/20170405034239/https://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4356s2-02-FDA-corepresentations_files/frame.htm.

Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."[159]

5. Cephalon Funded False Publications and Presentations

247. In addition to its direct marketing, Cephalon indirectly marketed through third parties to change the way doctors viewed and prescribed opioids – disseminating the unproven and deceptive messages that opioids were safe for the treatment of chronic long-term pain, that they were non-addictive and that they were woefully under-prescribed to the detriment of patients who were needlessly suffering. It did so by sponsoring pro-opioid front groups, misleading prescription guidelines, articles and CME programs, and it paid physicians thousands of dollars every year to publicly opine that opioids were safe, effective and non-addictive for a wide variety of uses.

248. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC ("Medscape"), and which disseminated false and misleading information to physicians in the geographic region served by Plaintiff and across the country.

249. For example, a 2003 Cephalon-sponsored CME presentation titled "Pharmacologic Management of Breakthrough or Incident Pain," posted on Medscape in February 2003, teaches:

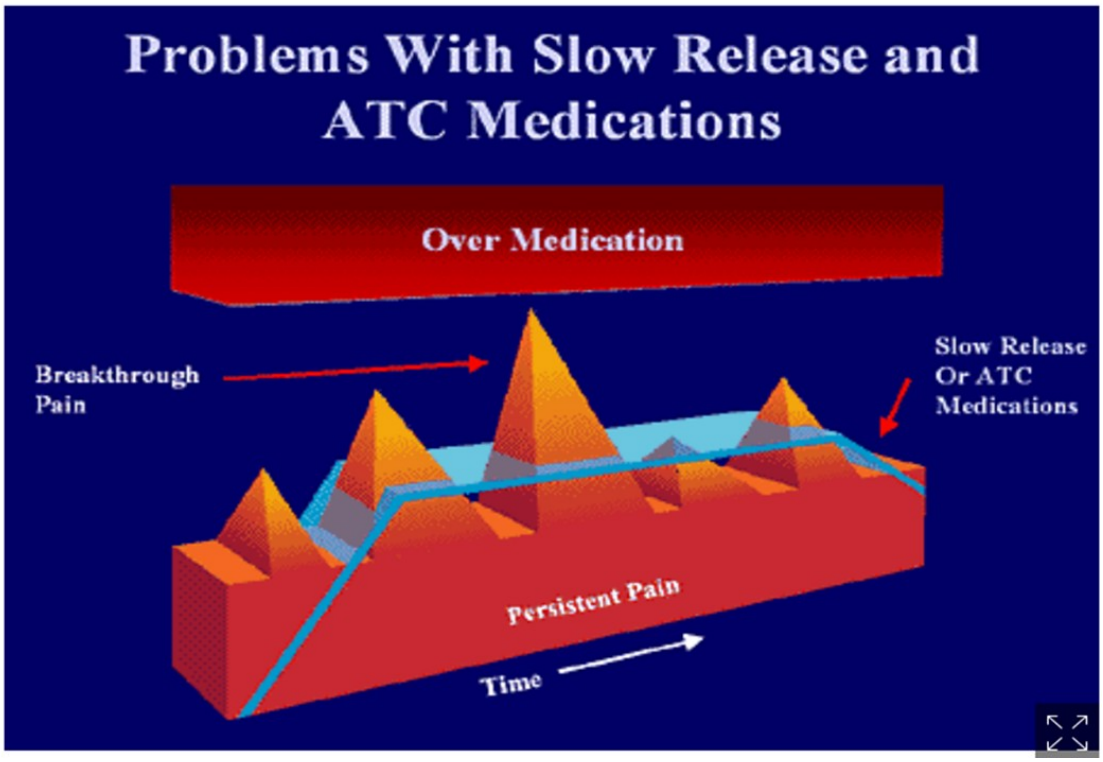
[159] *An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)*, Pharmacy Times (Jan. 13, 2012), http://www.pharmacytimes.com/publications/issue/2012/january2012/r514-jan-12-rems.

> ***Chronic pain is often undertreated, particularly in the noncancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.***[160]

250. Another Cephalon-sponsored CME presentation, titled "Breakthrough Pain: Treatment Rationale with Opioids," was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who "previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis." He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using "targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway."[161] The doctor lists fentanyl as one of the most effective opioids available for treating BTP, describing its use as an expected and normal part of the pain management process. Nowhere in the CME presentation is cancer or cancer pain mentioned.

[160] Michael J. Brennan, *et al.*, *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape, https://www.medscape.org/viewarticle/449803 (last visited Mar. 14, 2018).

[161] Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, https://www.medscape.org/viewarticle/461612 (last visited Mar. 14, 2018).



251. Dr. Stephen H. Landy ("Landy") authored a 2004 CME manuscript available on Medscape titled "Oral Transmucosal Fentanyl Citrate for the Treatment of Migraine Headache Pain In Outpatients: A Case Series." The manuscript preparation was supported by Cephalon. Landy describes the findings of a study of fentanyl citrate for the use of migraine headache pain and concluded that "OTFC rapidly and significantly relieved acute, refractory migraine pain in outpatients . . . and was associated with high patient satisfaction ratings."[162] Based on an analysis of publicly available data, Cephalon paid Landy approximately $190,000 in 2009-2010 alone, and in 2015-2016, Cephalon paid Landy another $75,000.

252. In 2006, Cephalon sponsored a review of scientific literature to create additional fentanyl-specific dosing guidelines titled "Evidence-Based Oral Transmucosal Fentanyl Citrate

[162] Stephen H. Landy, *Oral Transmucosal Fentanyl Citrate for the Treatment of Migraine Headache Pain In Outpatients: A Case Series*, 44(8) Headache (2004), https://www.medscape.com/viewarticle/488337_2.

(OTFC®) Dosing Guidelines."[163] The article purports to review the evidence for dosing and efficacy of oral transmucosal fentanyl citrate in the management of pain and produce dosing guidelines in both cancer and non-cancer patients. In pertinent part, it states:

> Oral transmucosal fentanyl citrate has a proven benefit in treating cancer-associated breakthrough pain in opioid-tolerant patients with cancer, which is the Food and Drug Administration (FDA)-approved indication for Actiq. ***Pain medicine physicians have also used OTFC successfully to provide rapid pain relief in moderate to severe noncancer pain in both opioid-tolerant and opioid-nontolerant patients.***[164]

253. Deeper into the article, the authors attempt to assuage doctors' concerns regarding possible overdose and respiratory distress in non-cancer patients by arguing "***[t]here is no evidence that opioid safety and efficacy differs in opioid-tolerant patients with chronic noncancer pain***." Regarding the use of fentanyl to treat non-opioid-tolerant patients, the article's authors stated:

> Alternatively, ***OTFC might also be used cautiously and safely for acute pain experienced by patients who are not opioid tolerant. Parenteral opioids are routinely used for acute pain in patients who are not opioid tolerant***. Examples include episodic pain (i.e., refractory migraine pain, recurrent renal calculi, etc.) and acute pain that follows surgery, trauma, or painful procedures (burn dressing change, bone marrow aspiration, lumbar puncture). Assuming that clinical experience with IV morphine in patients who are not opioid tolerant can be extrapolated, OTFC should be safe and efficacious in such settings as well.[165]

254. Through its sponsorship of the FSMB's "Responsible Opioid Prescribing: A Physician's Guide" (*see supra* ¶¶44-49), Cephalon continued to encourage the prescribing of opioid medication to "reverse . . . and improve" patient function, attributing patients' displays of traditional drug-seeking behaviors as merely "pseudo addiction."

255. Cephalon also disseminated its false messaging through speakers' bureaus and

---

[163] Gerald M. Aronoff, *et al.*, *Evidence-Based Oral Transmucosal Fentanyl Citrate (OTFC) Dosing Guidelines*, 6(4) Pain Med. 305-14 (Aug. 2005).
[164] *Id.*
[165] *Id.*

publications. For example, at an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results." The presentation's agenda description states: "Most patients with chronic pain experience episodes of breakthrough pain (BTP), yet no currently available pharmacologic agent is ideal for its treatment." The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the "[i]nterim results of this study suggest that FEBT is safe and well-tolerated in patients with chronic pain and BTP."

256. Cephalon sponsored another CME activity written by Webster and M. Beth Dove titled "Optimizing Opioid Treatment for Breakthrough Pain" and offered on Medscape from September 28, 2007 through December 15, 2008. The CME activity teaches that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating BTP than pure opioid analgesics because of dose limitations on the non-opioid component.[166]

257. Fine authored a Cephalon-sponsored CME article titled "Opioid-Based Management of Persistent and Breakthrough Pain" with Drs. Christine A. Miaskowski and Michael J. Brennan. Cephalon paid to have this CME article published in a "Special Report" supplement of the journal *Pain Medicine News* in 2009.[167] The CME article targeted a wide variety of non-oncologist healthcare providers who treat patients with chronic pain with the objective of educating "health care professionals about a semi-structured approach to the opioid-based management of persistent and

[166] Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, Medscape, https://www.medscape.org/viewarticle/563417_6 (last visited Mar. 14, 2018).
[167] Perry G. Fine, *et al*., *Opioid-Based Management of Persistent and Breakthrough Pain*, Special Report (2009), https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain/9.

breakthrough pain," including the use of fentanyl. The CME article purports to analyze the "combination of evidence- and case-based discussions" and ultimately concludes:

> Chronic pain is a debilitating biopsychosocial condition prevalent in both cancer and noncancer pain populations. . . .Opioids have an established role in pain related to cancer and other advanced medical illnesses, as well as an increasing contribution to the long-term treatment of carefully selected and monitored patients with certain [chronic noncancer pain] conditions. ***All individuals with chronic, moderate to severe pain associated with functional impairment should be considered for a trial or opioid therapy, although not all of them will be selected.***[168]

258. Along with Purdue, Cephalon sponsored APF's guide (*see supra* ¶¶62, 64), which warned against the purported ***under***-prescribing of opioids, taught that addiction is ***rare*** and suggested that opioids have "***no ceiling dose***" and are therefore the most appropriate treatment for severe pain.

259. A summary of the February 12-16, 2008 AAPM annual meeting reinforced the message, promoted both by the AAPM and the APS, that "the undertreatment of pain is unjustified." It continues:

> ***Pain management is a fundamental human right*** in all patients not only with acute postoperative pain but also ***in patients suffering from chronic pain***. Treating the underlying cause of pain does not usually treat all of the ongoing pain. Minimal pathology with maximum dysfunction remains the enigma of chronic pain. Chronic pain is only recently being explored as a complex condition that requires individual treatment and a multidisciplinary approach. It is considered to be a disease entity.[169]

260. Cephalon was one of several opioid manufacturers who collectively paid 14 of the 21 panel members who drafted the 2009 APS-AAPM opioid treatment guidelines.[170]

261. In the March 2007 article titled "Impact of Breakthrough Pain on Quality of Life in

---

[168] *Id.*
[169] Mohamed A. Elkersh & Zahid H. Bajwa, *Highlights From the American Academy of Pain Medicine 24th Annual Meeting*, 2(1) Advances in Pain Management 50-52 (2008).
[170] *See* Chou, *Clinical Guidelines*, *supra* n.71.

Patients with Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate,"[171] published in the nationally circulated journal *Pain Medicine*, physicians paid by Cephalon (including Webster) described the results of a Cephalon-sponsored study seeking to expand the definition of BTP to the chronic non-cancer setting. The authors stated that the "OTFC has been shown to relieve BTP more rapidly than conventional oral, normal-release, or 'short acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of noncancer pain patients."[172] The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

> In summary, BTP appears to be a clinically important condition in patients with ***chronic noncancer pain*** and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP ***and the potential benefits of BTP- specific therapy*** suggests several domains that may be helpful in developing BTP- specific, QoL assessment tools.[173]

262. Cephalon also sponsored, through an educational grant, the regularly published journal *Advances in Pain Management*. In a single 2008 issue of the journal, there are numerous articles from Portenoy, Dr. Steven Passik ("Passik"), Dr. Kenneth L. Kirsh ("Kirsh") and Webster, all advancing the safety and efficacy of opioids. In an article titled "Screening and Stratification Methods to Minimize Opioid Abuse in Cancer Patients," Webster expresses disdain for the prior 20 years of opioid phobia.

263. In another article from the same issue, "Appropriate Prescribing of Opioids and

---

[171] Donald R. Taylor, *et al.*, *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ)*, 8(3) Pain Med. 281-88 (Mar. 2007).
[172] *Id.*
[173] *Id.*

Associated Risk Minimization," Passik and Kirsh state: "[c]hronic pain, currently experienced by approximately 75 million Americans, is becoming one of the biggest public health problems in the US." They assert that addiction is rare, that "[m]ost pain specialists have prescribed opioids for long periods of time with success demonstrated by an improvement in function," and that then-recent work had shown "that opioids do have efficacy for subsets of patients who can remain on them long term and have very little risk of addiction."[174]

264. In November 2010, Fine and others published an article presenting the results of another Cephalon-sponsored study titled "Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study."[175] In that article, Fine explained that the 18-month "open-label" study "assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort…of opioid-tolerant patients receiving around-the-clock...opioids for noncancer pain." The article acknowledged that: (a) "[t]here has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades"; (b) the "widespread acceptance" had led to the publishing of practice guidelines "to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain"; and (c) those guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain."[176]

265. They conclude: "[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable." They also conclude that the number of abuse-related events was

[174] Steven D. Passik & Kenneth L. Kirsh, *Appropriate Prescribing of Opioids and Associated Risk Minimization*, 2(1) Advances in Pain Management 9-16 (2008).
[175] Perry G. Fine, *et al.*, *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) J. Pain & Symptom Management 747-60 (Nov. 2010).
[176] *Id.*

"small."[177]

266. From 2000 forward, Cephalon has paid doctors nationwide millions of dollars for programs relating to its opioids, many of whom were not oncologists and who did not treat cancer pain. These doctors included Portenoy, Webster, Fine, Passik, Kirsh, Landy and others.

267. Fentora has been widely prescribed in the geographic region served by Plaintiff. According to data collected by *ProPublica*, during 2014 and 2015, Florida doctors' prescriptions of Fentora to patients insured by the Medicare Part D program totaled more than $2.3 million in 2014 and almost $3.6 million in 2015.

268. Cephalon's payments to doctors have resulted in studies that support its sales, but, on closer examination, are biased or irreparably flawed. For instance, and upon information and belief, the governmental whistleblower investigation into Actiq revealed that two studies touted by Cephalon had tested fewer than 28 patients and had no control group whatsoever.[178] A 2012 article evaluating the then-current status of transmucosal fentanyl tablet formulations for the treatment of BTP in cancer patients noted that clinical trials to date used varying criteria, that "the approaches taken . . . [did] not uniformly reflect clinical practice," and that "the studies ha[d] been sponsored by the manufacturer and so ha[d] potential for bias."[179]

6. Cephalon Failed to Report Suspicious Sales as Required

269. The federal CSA imposes on all "registrants" the obligation to design and operate a system to disclose to the registrant suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and

[177] *Id.*
[178] Carreyrou, *Cephalon Used Improper Tactics*, *supra* n.186.
[179] Eric Prommer & Brandy Fleck, *Fentanyl Transmucosal Tablets: Current Status in the Management of Cancer-Related Breakthrough Pain*, 2012(6) Patient Preference and Adherence 465-75 (June 25, 2012).

orders of unusual frequency." 21 C.F.R. §1301.74(b).

270. Cephalon is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

271. Cephalon failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Cephalon's failure to timely report suspicious sales violated the CSA.

E. Non-Party Insys

272. Non-Party Insys manufactures, markets, sells and distributes the following pharmaceutical drug in the geographic region served by Plaintiff and nationwide:

Subsys (fentanyl)	Fentanyl sublingual spray; semi-synthetic opioid agonist, approved in 2012.	Schedule II

273. Subsys is indicated "for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain."[180] The indication also specifies that "SUBSYS is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain." In addition, the indication provides that "[p]atients must remain on around-the-clock opioids when taking SUBSYS." Subsys is contraindicated for, among other ailments, the "[m]anagement of acute or postoperative pain including headache/migraine and dental pain." It is available in 100 mcg, 200 mcg, 400 mcg, 600 mcg and 800 mcg dosage strengths.

[180] The indication provides that "[p]atients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer."

274. Non-Party Insys' revenue is derived almost entirely from Subsys. According to its Form 10-K for 2015, Insys reported revenues of $331 million. Of that total, $329.5 million was derived from sales of Subsys. Subsys has been widely prescribed in the geographic region served by Plaintiff. According to data collected by *ProPublica*, during 2014 Florida doctors' prescriptions of Subsys to patients insured by the Medicare Part D program totaled more than $15 million, and in 2015, Subsys Medicare Part D prescriptions totaled more than $28.1 million. The majority of Insys' sales of Subsys are through wholesalers, including Defendants AmerisourceBergen, McKesson and Cardinal Health. In 2015, those wholesalers respectively comprised 20%, 17% and 14% of Insys' total gross sales of Subsys.

275. According to Dr. Andrew Kolodny, executive director of Physicians for Responsible Opioid Prescribing and chief medical officer of the Phoenix House Foundation, fentanyl products are "'the most potent and dangerous opioids on the market.'"[181]

276. The dangers associated with Subsys are reflected by its extremely limited and specific indication, as it is approved solely for BTP in cancer patients already receiving opioids for persistent cancer-related pain.

277. Despite Subsys' limited indication and the potent danger associated with fentanyl, Insys falsely and misleadingly marketed Subsys to doctors as an effective treatment for back pain, neck pain and other off-label pain conditions.[182] Moreover, as of June 2012, Insys defined BTP in cancer patients to include mild pain: a "flare of ***mild-to***-severe pain in patients with otherwise stable persistent pain," based on a misleading citation to a paper written by Portenoy.[183] Insys trained and

[181] Dina Gusovsky, *The pain killer: A drug company putting profits above patients*, CNBC (Nov. 5, 2015), available at https://www.cnbc.com/2015/11/04/the-deadly-drug-appeal-of-insys-pharmaceuticals.html.
[182] *In the Matter of Insys Therapeutics, Inc.*, Notice of Unlawful Trade Practices and Proposed Resolution (July 10, 2015), available at https://www.documentcloud.org/documents/2195731-insysdoj.html.
[183] Portenoy's paper, "Breakthrough pain: definition, prevalence and characteristics," which was featured in the 1990 issue of *Pain*, actually defined breakthrough pain as "a transitory increase in pain to greater than

instructed its sales representatives to use the false definition of breakthrough pain and specifically to use a core visual aid, which included the improper definition, whenever they detailed Subsys to a healthcare provider or provider's office.

278. According to a 2014 article in *The New York Times*, only 1% of prescriptions for Subsys were written by oncologists. Approximately half the prescriptions were written by pain specialists, with others written by other specialists including dentists and podiatrists.[184]

1. The Indictment of Non-Party Insys Executives and Arrest of Its Founder

279. On December 8, 2016, several former Insys executives were arrested and indicted for conspiring to bribe practitioners in numerous states, many of whom operated pain clinics, in order to get them to prescribe Subsys. In exchange for bribes and kickbacks, the practitioners wrote large numbers of prescriptions for patients, most of whom were not diagnosed with cancer.[185]

280. The indictment alleged that the former executives conspired to mislead and defraud health insurance providers, who were reluctant to approve payment for Subsys when it was prescribed for patients without cancer. In response, the former executives established a "reimbursement unit" at Insys, which was dedicated to assisting physicians by obtaining prior authorization for prescribing Subsys directly from insurers and pharmacy benefit managers. Insys' reimbursement unit employees were told to inform agents of insurers and pharmacy benefit

---

moderate intensity (that is, to an intensity of 'severe' or 'excruciating') . . . on a baseline pain of moderate intensity or less." Russell K. Portenoy & Neil A. Hagen, *Breakthrough pain: Definition, prevalence and characteristics*, 41(3) Pain 273-81 (July 1990).

[184] Katie Thomas, *Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller*, *N.Y. Times* (May 13, 2014), available at https://www.nytimes.com/2014/05/14/business/doubts-raised-about-off-label-use-of-subsys-a-strong-painkiller.html?action=click&contentCollection=Business%20Day&region=Footer&module=MoreInSection&pgtype=Blog%20s&_r=2.

[185] Press Release, U.S. Attorney's Office for the District of Massachusetts, Pharmaceutical Executives Charged in Racketeering Scheme (Dec. 8, 2016), https://www.justice.gov/usao-ma/pr/pharmaceutical-executives-charged-racketeering-scheme (hereinafter "*Insys* Indictment Press Release"); *United States v. Babich, et al.*, No. 1:16-cr-10343-ADB, Dkt. No. 1 (D. Mass. Dec. 6, 2016), https://www.justice.gov/usao-ma/press-release/file/916681/download (hereinafter "*Insys* Indictment").

managers that they were calling "from" or that they were "with" the doctor's office, or that they were calling "on behalf of" the doctor.

281. The executive Defendants in the indictment are Insys' former chief executive officer and president, former vice president of sales, former national director of sales, former vice president of managed markets and several former regional sales directors. On October 26, 2017, the billionaire founder, chief executive officer, and chairman of Insys, John Kapoor, who owns a 60% stake in the company, was also charged with fraud and racketeering and was accused of offering bribes to doctors to write large numbers of prescriptions for Subsys. Most of the patients who received the medication did not have cancer.[186]

282. The charges against all seven executives include alleged violations of the federal Anti-Kickback Law, the federal Racketeer Influenced and Corrupt Organizations ("RICO") statute and conspiracy to commit wire and mail fraud, as well as allegations of bribery and defrauding insurers. If found guilty, the Defendants face possible sentences of up to 20 years for conspiracy to commit RICO and conspiracy to commit mail and wire fraud, as well as a fine of $250,000 or twice the amount of the pecuniary gain or loss. For the charge of conspiracy to violate the Anti-Kickback Law, the Defendants face a sentence of up to five years in prison and a $25,000 fine.

283. The indictment details a coordinated, centralized scheme by Insys to illegally drive profits. The company defrauded insurers from a call center at corporate headquarters where Insys employees, acting at the direction of Insys' former chief executive officer and vice president of managed markets, disguised their identity and the location of their employer and lied about patient diagnoses, the type of pain being treated and the patients' course of treatment with other medication.

[186] Michela Tindera, *Opioid Billionaire Arrested on Racketeering Charges*, Forbes (Oct. 26, 2017), available at https://www.forbes.com/sites/michelatindera/2017/10/26/opioid-billionaire-arrested-on-racketeering-charges/#3ab43aad6a00 (hereinafter "Tindera, *Opioid Billionaire Arrested*").

284. Harold Shaw, special agent in charge of the FBI Boston field division, said in a statement, "As alleged, these executives created a corporate culture at Insys that utilized deception and bribery as an acceptable business practice, deceiving patients, and conspiring with doctors and insurers."[187]

2. Non-Party Insys Targeted Non-Cancer Treating Physicians and Funded False Publications and Presentations

285. As set forth in the above-referenced indictment, Non-Party Insys targeted and bribed practitioners in a number of ways. Insys bribed Subsys prescribers through strategic hires and by employing sales representatives and other employees at practitioners' behest, with the expectation that such hires would provide inroads with key practitioners. Insys also bribed practitioners through a sham speakers' bureau that was purportedly intended to increase brand awareness using peer-to-peer educational lunches and dinners.

286. Specifically, in June 2012, former executives began using in-person meetings, telephone calls and texts to inform Insys sales representatives that the key to sales was using the speakers' bureau to pay practitioners to prescribe Subsys. As one of the company's vice presidents for sales texted one of his sales representatives about potential physicians for the speakers' bureau: "[t]hey do not need to be good speakers, they need to write a lot of [Subsys prescriptions]." The former Insys executives actively recruited physicians known to have questionable prescribing habits for these speakers' bureaus.[188]

287. The speakers' bureaus were often just social gatherings at high-priced restaurants involving neither education nor presentations. Frequently, they involved repeat attendees, including physicians not licensed to prescribe Subsys. Many of the speakers' bureaus had no attendees; sales

[187] *Id.*
[188] *Insys* Indictment Press Release, *supra* n.216.

representatives were instructed to falsely list names of attendees and their signatures on Insys' sign-in sheets.

288. Moreover, the executives are charged with targeting practitioners who prescribed Subsys not only for cancer pain, but for all pain.

289. As set forth in the indictment, at one national speakers' bureau in or about 2014, Insys' then-vice president of sales stated:

> "These [doctors] will tell you all the time, well, I've only got like eight patients with cancer. Or, I only have, like, twelve patients that are on a rapid-onset opioids [sic]. Doc, I'm not talking about any of those patients. I don't want any of those patients. That's, that's small potatoes. That's nothing. That's not what I'm here doing. I'm here selling [unintelligible] for the breakthrough pain. If I can successfully sell you the [unintelligible] for the breakthrough pain, do you have a thousand people in your practice, a thousand patients, twelve of them are currently on a rapid-onset opioids [sic]. ***That leaves me with at least five hundred patients that can go on this drug.***"[189]

290. Moreover, when agents of insurers or pharmacy benefit managers asked if a patient was being treated for BTP in cancer patients, Insys' reimbursement unit employees were instructed to answer using a written script, sometimes called "the spiel": "'The physician is aware that the medication is intended for the management of breakthrough pain in cancer patients. The physician is treating the patient for their pain (or breakthrough pain, whichever is applicable).'"[190]

291. Non-Party Insys' former executives also tracked and internally circulated the number of planned and completed speakers' bureau events for each speaker, as well as the number of Subsys prescriptions each speaker wrote, the percentage of such prescriptions compared to those written for Subsys' competitor drugs, the total amount of honoraria paid to each speaker and, for a period of time, an explicit calculation of the ratio of return on investment for each speaker. When a speaker did not write an appropriately large number of Subsys prescriptions, as determined by Insys, the

[189] *Insys* Indictment, *supra* n.216, at 15.
[190] *Id.* at 44.

number of future events for which that speaker would be paid would be reduced unless and until he or she wrote more Subsys prescriptions.

292. In a press release issued when the indictment was announced, the Massachusetts U.S. Attorney, Carmen M. Ortiz, stated: "'I hope that today's charges send a clear message that we will continue to attack the opioid epidemic from all angles, whether it is corporate greed or street level dealing.'"[191]

293. In the same press release, the FBI Special Agent in Charge of the Boston field division, Harold H. Shaw, linked the allegations to the national opioid epidemic:

> ***As alleged, top executives of Insys Therapeutics, Inc. paid kickbacks and committed fraud to sell a highly potent and addictive opioid that can lead to abuse and life threatening respiratory depression…. In doing so, they contributed to the growing opioid epidemic and placed profit before patient safety. These indictments reflect the steadfast commitment of the FBI and our law enforcement partners to confront the opioid epidemic impacting our communities, while bringing to justice those who seek to profit from fraud or other criminal acts***.[192]

294. The Special Agent in Charge at the Defense Criminal Investigative Service in the Northeast Field Office, Craig Rupert, commented specifically on the effect the criminal activities had on members of the military: "'Causing the unnecessary use of opioids by current and retired military service members shows disregard for their health and disrespect for their service to our country….'"[193]

3. Non-Party Insys Failed to Report Suspicious Sales as Required

295. The federal CSA imposes on all "registrants" the obligation to design and operate a system to disclose to the registrant suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious

[191] *Insys* Indictment Press Release, *supra* n.216.
[192] *Id.*
[193] *Id.*

orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

296. Non-Party Insys is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

297. Non-Party Insys failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Insys' failure to timely report suspicious sales violated the CSA.

F. Non-Party Mallinckrodt

298.

Exalgo (hydromorphone hydrochloride extended release)	Opioid agonist indicated for opioid-tolerant patients for management of pain severe enough to require daily, around- the-clock, long-term opioid treatment and for which alternative treatment options (*e.g.*, non-opioid analgesics) are inadequate. The FDA approved the 8, 12, and 16 mg tablets of Exalgo in March 2010 and 32 mg tablet in August 2012.	Schedule II
Roxicodone (oxycodone hydrochloride)	Brand-name instant-release form of oxycodone hydrochloride. Indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Acquired from Xanodyne Pharmaceuticals in 2012. Strengths range up to 30 mg per pill. Nicknames include Roxies, blues, and stars.	Schedule II
Xartemis XR (oxycodone hydrochloride and acetaminophen)	The FDA approved Xartemis XR in March 2014 for the management of acute pain severe enough to require opioid treatment and in patients for whom alternative treatment options are ineffective, not tolerated or would otherwise be inadequate. It was the first extended-release oral combination of oxycodone and acetaminophen.	Schedule II
Methadose (methadone hydrochloride)	Branded generic product. Opioid agonist indicated for treatment of opioid addiction.	Schedule II
Morphine sulfate extended release	Generic product.	Schedule II

Fentanyl extended release	Generic product.	Schedule II
Fentanyl citrate	Generic product.	Schedule II
Oxycodone and acetaminophen	Generic product.	Schedule II
Hydrocodone bitartrate and acetaminophen	Generic product.	Schedule II
Hydromorphone hydrochloride	Generic product.	Schedule II
Hydromorphone hydrochloride extended release	Generic product.	Schedule II
Naltrexone hydrochloride	Generic product.	Schedule II
Oxymorphone hydrochloride	Generic product.	Schedule II
Methadone hydrochloride	Generic product.	Schedule II
Oxycodone hydrochloride	Generic product.	Schedule II

299. Mallinckrodt purchased Roxicodone from Xanodyne Pharmaceuticals in 2012.[194]

300. Mallinckrodt debuted Xartemis (MNK-795) at the September 4-7, 2013 PAINWeek in Las Vegas.

1. Non-Party Mallinckrodt Funded False Publications and Presentations

301. Like several of the other Manufacturing Defendants, Non-Party Mallinckrodt provided substantial funding to purportedly neutral organizations, which disseminated false messaging about opioids.

302. For example, until at least February 2009, Non-Party Mallinckrodt provided an educational grant to Pain-Topics.org, a now-defunct website that touted itself as "a noncommercial resource for

[194] *Mallinckrodt Announces Agreement with Xanodyne to Purchase Roxicodone*, Bus. Wire (Aug. 23, 2012), available at https://www.businesswire.com/news/home/20120823005209/en/Mallinckrodt-Announces-Agreement-Xanodyne-Purchase-Roxicodone%C2%AE.

healthcare professionals, providing open access to clinical news, information, research, and education for a better understanding of evidence-based pain-management practices."[195]

303. Among other content, the website included a handout titled "Oxycodone Safety Handout for Patients," which advised practitioners that: "Patients' fears of opioid addiction should be dispelled."[196] The handout included several false and misleading statements concerning the risk of addiction associated with prescription opioids:

> Will you become dependent on or addicted to oxycodone?
>
> - After a while, oxycodone causes physical dependence. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.
>
> - This is not the same as addiction, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.[197]

304. Additionally, the FAQ section of Pain-Topics.org contained the following false and misleading information downplaying the dangers of prescription opioid use:

> **Pseudoaddiction** – has been used to describe aberrant patient behaviors that may occur when pain is undertreated (AAPM 2001). Although this diagnosis is not supported by rigorous investigation, it has been widely observed that patients with unrelieved pain may become very focused on obtaining opioid medications, and may be erroneously perceived as "drug seeking." Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated. Along with this, two related phenomena have been described in the literature (Alford et al. 2006):
>
> > **Therapeutic dependence** – sometimes patients exhibit what is considered drug-seeking because they fear the reemergence of pain and/or withdrawal symptoms from lack of adequate medication; their

[195] *Pain Treatment Topics*, Pain-Topics.org, available at https://web.archive.org/web/20070104235709/http://www.pain-topics.org:80/ (last visited Mar. 14, 2018).
[196] Lee A. Kral & Stewart B. Leavitt, *Oxycodone Safety Handout for Patients*, Pain-Topics.Org (June 2007), available at http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.
[197] *Id.*

> ongoing quest for more analgesics is in the hopes of insuring a tolerable level of comfort.
>
> **Pseudo-opioid-resistance** – other patients, with adequate pain control, may continue to report pain or exaggerate its presence, as if their opioid analgesics are not working, to prevent reductions in their currently effective doses of medication.
>
> Patient anxieties about receiving inadequate pain control can be profound, resulting in demanding or aggressive behaviors that are misunderstood by healthcare practitioners and ultimately detract from the provision of adequate pain relief.[198]

305. Another document available on the website, "Commonsense Oxycodone Prescribing & Safety," falsely suggests that generic oxycodone is less prone to abuse and diversion than branded oxycodone: "Anecdotally, it has been observed that generic versions of popularly abused opioids usually are less appealing; persons buying drugs for illicit purposes prefer brand names because they are more recognizable and the generics have a lower value 'on the street,' which also makes them less alluring for drug dealers."[199]

306. In November 2016, Mallinckrodt paid Dr. Scott Gottlieb ("Gottlieb"), the new commissioner of the FDA, $22,500 for a speech in London, shortly after the U.S. presidential election.[200] Gottlieb has also received money from the Healthcare Distribution Alliance ("HDA"), an industry-funded organization that pushes the agenda of large pharmaceutical wholesalers, and he has often criticized efforts aimed at regulating the pharmaceutical opioid market.[201]

307. Exalgo, Roxicodone and Xartemis XR have been widely prescribed in the geographic region served by Plaintiff. According to data collected by ProPublica, in 2014, Florida doctors'

---

[198] *FAQs*, Pain-Topics.org, available at, https://web.archive.org/web/20070709031530/http://www.pain-topics.org:80/faqs/index1.php#tolerance

[199] Lee A. Kral, *Commonsense Oxycodone Prescribing & Safety*, Pain-Topics.org (June 2007), available at http://paincommunity.org/blog/wp-content/uploads/OxycodoneRxSafety.pdf.

[200] Lee Fang, *Donald Trump's Pick to Oversee Big Pharma Is Addicted to Opioid-Industry Cash*, Intercept (Apr. 4, 2017), available at https://theintercept.com/2017/04/04/scott-gottlieb-opioid/.

[201] *Id.*

prescriptions of Exalgo to patients insured by the Medicare Part D program totaled almost $3.8 million, prescriptions of Roxicodone totaled more than $265,000, and prescriptions of Xartemis XR totaled almost $9,000. In 2015, those numbers were more than $1.5 million for Exalgo, almost $292,000 for Roxicodone, and approximately $15,000 for Xartemis XR.

2. The DEA Investigates Suspicious Orders

308. In 2008, the DEA and federal prosecutors launched an investigation into Non-Party Mallinckrodt, charging that the company ignored red flags and supplied – and failed to report – suspicious orders for its generic oxycodone between 2008 and 2012.[202] The U.S. Attorney's office in Detroit handled the case. The investigation uncovered that from 2008 to 2012, Mallinckrodt sent, for example, 500 million tablets of oxycodone into a single state, Florida – "66 percent of all oxycodone sold in the state."[203] According to the internal government documents obtained by the Washington Post, Mallinckrodt's failure to report could have resulted in "nearly 44,000 federal violations and exposed it to $2.3 billion in fines."[204]

309. Despite learning from the DEA that generic opioids seized in a Tennessee drug operation were traceable to one of its Florida distributors, Sunrise Wholesale ("Sunrise") of Broward County, Mallinckrodt in the following six weeks sent 2.1 million tablets of oxycodone to Sunrise. In turn, Sunrise sent at least 92,400 oxycodone tablets to a single doctor over an 11-month period, who, in one day, prescribed 1,000 to a single patient.[205]

310. According to documents obtained by the *Washington Post*, investigators also found "scores of alleged violations" at Mallinckrodt's plant in Hobart, New York. Those violations

[202] Lenny Bernstein & Scott Higham, *The government's struggle to hold opioid manufacturers accountable*, Wash. Post (Apr. 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.7ce8c975dd86.
[203] *Id.*
[204] *Id.*
[205] *Id.*

included the failure to keep accurate records, to document transfers of drugs and to secure narcotics.[206]

311. During the DEA's investigation, Non-Party Mallinckrodt sponsored the HDA (known as the Healthcare Distribution Management Association until 2016), an industry-funded organization that represents pharmaceutical distributors.[207] The HDA initiated the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (enacted April 19, 2016), which requires the DEA to give notice of violation and an opportunity to comply, to pharmacies and distributors, before withdrawing licenses. This Act substantially lessened the DEA's ability to regulate manufacturers and wholesalers.[208]

312. In May 2014, Mallinckrodt posted a video titled "Red Flags: Pharmacists Anti-Abuse Video." The video is a thinly veiled attempt to divert responsibility for the opioid epidemic away from manufacturers and wholesalers, and toward individual pharmacists. The video was sponsored by the Anti-Diversion Industry Working Group, which is composed of Cardinal Health, Actavis, McKesson, Mallinckrodt, AmerisourceBergen, and Qualitest—all of whom are conveniently missing from the list of those responsible.[209]

313. In April 2017, Non-Party Mallinckrodt reached an agreement with the DEA and the U.S. Attorneys for the Eastern District of Michigan and Northern District of New York to pay

---

[206] *Id.*

[207] *Sponsors: HDA's Annual Circle Sponsors*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/hda-sponsors (last visited Mar. 14, 2018).

[208] Chris McGreal, *Opioid epidemic: ex-DEA official says Congress is protecting drug makers*, Guardian (Oct. 31, 2016), https://www.theguardian.com/us-news/2016/oct/31/opioid-epidemic-dea-official-congress-big-pharma.

[209] Mallinckrodt Pharmaceuticals, *Red Flags: Pharmacists Anti-Abuse Video*, YouTube (May 27, 2014), https://www.youtube.com/watch?v=fdv0B210bEk&amp=&t=1s. (last available source).

$35 million to resolve a probe of its distribution of its opioid medications.[210] Mallinckrodt finalized the settlement on July 11, 2017, agreeing to pay $35 million while admitting no wrongdoing.[211]

3. Non-Party Mallinckrodt Failed to Report Suspicious Sales as Required

314. The federal CSA imposes on all "registrants" the obligation to design and operate a system to disclose to the registrant suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

315. Non-Party Mallinckrodt is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

316. Non-Party Mallinckrodt failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Mallinckrodt's failure to timely report suspicious sales violated the CSA.

317. As part of their deceptive marketing scheme, the Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the United States, Florida, and in the geographic region served by Plaintiff. For example, these Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs.

---

[210] Linda A. Johnson, *Mallinckrodt to Pay $35M in Deal to End Feds' Opioid Probe*, U.S. News & World Report (Apr. 3, 2017), https://www.usnews.com/news/business/articles/2017-04-03/mallinckrodt-to-pay-35m-in-deal-to-end-feds-opioid-probe.

[211] Press Release, U.S. Department of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

318. The Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. These Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for these Defendants' deceptive messages was not apparent to medical professionals who relied on them in making treatment decisions, nor could it have been detected by Plaintiff.

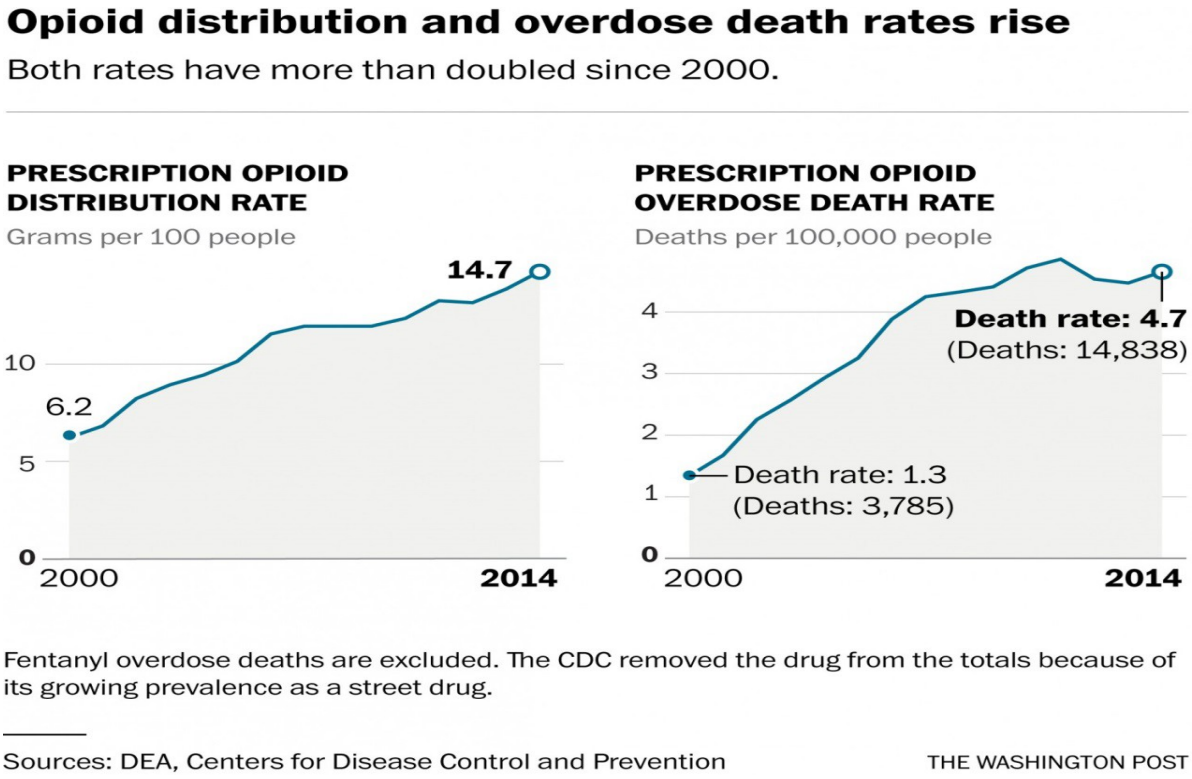
319. Thus, the Manufacturer Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the claims now asserted by Plaintiff. Plaintiff did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

320. The Manufacturer Defendants' deceptive marketing scheme causes and continues to cause doctors in Florida, and specifically in the geographic region served by Plaintiff, to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent these Defendants' deceptive marketing schemes, these doctors would not have prescribed as many opioids. These Defendants' deceptive marketing schemes also caused and continue to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent these Defendants' deceptive marketing schemes, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

321. The escalating number of opioid prescriptions written by doctors who were deceived by the Manufacturer Defendants' deceptive marketing schemes is the cause of a correspondingly dramatic increase in opioid addiction, overdose and death throughout the United States, Florida, and in the geographic region served by Plaintiff.

III. The Wholesaler Defendants Failed to Track and Report Suspicious Sales as Required by Florida and Federal Law

322. Manufacturers rely upon distributors to distribute their drugs. The distributors serve as middlemen, sending billions of doses of opioid pain pills to pharmacists, hospitals, nursing homes and pain clinics. According to the CDC, the increased distribution of opioids directly correlates to increased overdose death rates:



323. On October 23, 2017, CBS aired an episode of *60 Minutes* featuring former DEA agent Joe Rannazzisi, who blamed the Wholesaler Defendants for killing people by violating the CSA requirement to report suspicious orders:

> **RANNAZZISI:** This is an industry that's out of control. What they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die.
>
> This is an industry that allowed millions and millions of drugs to go into bad pharmacies and doctors' offices, that distributed them out to people who had no legitimate need for those drugs.

> **[INTERVIEWER]:** Who are these distributors?
>
> **RANNAZZISI:** The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.
>
> **[INTERVIEWER]:** You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> **RANNAZZISI:** That's not an implication, that's a fact. That's exactly what they did.

324. Jim Geldhof, a 40-year veteran of the DEA who ran investigations in the Detroit field office, corroborated Rannazzinsi's account, saying that the wholesalers are "absolutely" responsible for the opioids epidemic:

> **[INTERVIEWER]:** These companies are a big reason for this epidemic?
>
> **GELDHOF:** Yeah, absolutely they are. And I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us.

325. Indeed, according to Rannazzisi, the Wholesaler Defendants succeeded in lobbying Congress to strip the DEA of its most potent tool for fighting against diversion and abuse. In 2013, a bill was introduced in the House that "was promoted as a way to ensure that patients had access to the pain medication they needed." What it "really did," however, "was strip the [DEA] of its ability to immediately freeze suspicious shipments of prescription narcotics to keep drugs off U.S. streets." A 2015 DOJ memo confirmed that the bill "'could actually result in increased diversion, abuse, and public health and safety consequences.'"

326. During the two years the legislation was considered and amended, Defendants and others in the industry spent $102 million lobbying Congress on the bill and other legislation, "claiming the DEA was out of control [and] making it harder for patients to get needed medication." The APA co-signed a letter in support of the legislation. As discussed, *supra* ¶¶82-83, the APA

receives funding from numerous industry participants, including Johnson & Johnson, Endo, Mallinckrodt, Purdue and Cephalon. Metadata associated with the letter co-signed by the APA shows that it was created by Kristen L. Freitas, vice president for federal government affairs at the HDA – the trade group that represents Defendants McKesson, Cardinal Health, and AmerisourceBergen. Freitas is also a registered lobbyist who lobbied in support of the bill.

327. According to *60 Minutes*, the chief administrative law judge of the DEA, John J. Mulrooney, has written "that the new legislation 'would make it all but . . . impossible' to prosecute unscrupulous distributors." The proposed bill was signed into law in 2016. The primary author of the bill is former DEA associate chief counsel Linden Barber. He was recently hired by Cardinal Health as senior vice president.

A. McKesson

328. McKesson is a wholesale pharmaceutical distributor of controlled and uncontrolled prescription medications, including opioids. It is the largest drug distributor, and the fifth largest company, in the United States. It distributes pharmaceuticals through a network of distribution centers across the country. McKesson ranked fifth on the 2017 Fortune 500 list, with over $192 billion in revenues.

329. McKesson is a significant distributor of opioids in the United States and supplies various U.S. pharmacies with an increasing amount of oxycodone and hydrocodone pills, products frequently misused that are part of the current opioid epidemic.

330. McKesson distribution centers are required to operate in accordance with the statutory provisions of the CSA. The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "[s]uspicious orders" for controlled substances, as that term is defined in the regulation. *See* 21 C.F.R. §1301.74(b). The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. §1301.74(b). *See* 21 U.S.C. §842(a)(5) &

(c)(1)(B). The provision requiring the reporting of suspicious orders in the federal CSA has been incorporated into Florida law. Fla. Stat. §499.0121(10) and (15)(b).

331. In or about 2007, the DEA accused McKesson of failing to report suspicious orders and launched an investigation. In 2008, McKesson entered into a settlement agreement with the DOJ and a memorandum of agreement, agreeing to pay a $13.25 million fine for failure to report suspicious orders of pharmaceutical drugs and promising to set up a monitoring system.

332. As a result, McKesson developed a Controlled Substance Monitoring Program ("CSMP"), but nevertheless failed to design and implement an effective system to detect and report "suspicious orders" for controlled substances distributed to its independent and small-chain pharmacy customers – *i.e.*, orders that are unusual in their frequency, size or other patterns. McKesson continued to fail to detect and disclose suspicious orders of controlled substances. It failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the CSMP.

333. In 2013, the DEA again began investigating reports that McKesson was failing to maintain proper controls to prevent the diversion of opioids and accused McKesson of failing to design and use an effective system to detect "suspicious orders" from pharmacies for powerful painkillers such as oxycodone, as required by the CSA. Nine DEA field divisions and 12 U.S. Attorneys built a case against McKesson for the company's role in the opioid crisis, which David Schiller, Assistant Special Agent in Charge for the Denver Field Division and leader of the DEA team investigating McKesson, called "the best case we've ever had against a major distributor in the

history of the Drug Enforcement Administration."[212]

334. On December 17, 2017, CBS aired an episode of *60 Minutes* featuring Assistant Special Agent Schiller, who described McKesson as a company that killed people for its own financial gain and blatantly ignored the CSA requirement to report suspicious orders:

> **[SCHILLER:]** If they woulda stayed in compliance with their authority and held those that they're supplying the pills to, the epidemic would be nowhere near where it is right now. Nowhere near.
>
> * * *
>
> **[SCHILLER:]** They had hundreds of thousands of suspicious orders they should have reported, and they didn't report any. There's not a day that goes by in the pharmaceutical world, in the McKesson world, in the distribution world, where there's not something suspicious. It happens every day.
>
> **INTERVIEWER:]** And they had none.
>
> **[SCHILLER:]** They weren't reporting any. I mean, you have to understand that, nothing was suspicious?[213]

335. On January 17, 2017, in one of the most severe sanctions ever agreed to by a distributor, McKesson agreed to pay a record $150 million in fines and suspend sales of controlled substances from distribution centers in four states (Colorado, Ohio, Michigan and Florida) to settle allegations that the company violated federal law. According to the DOJ, McKesson continued to fail to report suspicious orders between 2008 and 2012 and did not fully implement or follow the monitoring program. As part of the agreement, McKesson acknowledged that:

> at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA.

---

[212] Bill Whitaker, *Whistleblowers: DEA attorneys went easy on McKesson, the country's largest drug distributor*, CBS News (Dec. 17, 2017), https://www.cbsnews.com/news/whistleblowers-dea-%20attorneys-went-easy-on-mckesson-the-countrys-largest-drug-distributor/.

[213] *Id.*

B. Cardinal Health

336. Cardinal Health describes itself as a global integrated healthcare services and products company. It generated $121.5 billion in total revenue during fiscal year 2016 (ended June 30, 2016). It is ranked 15th on the 2017 Fortune 500 list of top U.S. companies with revenues of over $121 billion.

337. Cardinal Health has two operating segments: pharmaceutical and medical. Its pharmaceutical segment, at issue in this action, distributes branded and generic pharmaceutical, special pharmaceutical, over-the-counter and consumer products in the United States. Of Cardinal Health's $121.5 billion in revenue during fiscal year 2016, $109.1 billion was derived from the pharmaceutical operating segment.

338. Cardinal Health is a significant distributor of opioids in the United States. Cardinal Health's largest customer is CVS Health ("CVS"), which accounted for 25% of Cardinal Health's fiscal year 2016 revenue. According to its website, CVS operates numerous pharmacies in the geographic region served by Plaintiff, and many more in nearby cities. Additionally, Cardinal Health runs a distribution center in Lakeland, Florida.[214]

339. Cardinal Health distribution centers are required to operate in accordance with the statutory provisions of the CSA and the regulations promulgated thereunder, 21 C.F.R. §1300 *et seq.* The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances as that term is defined in the regulation. *See* 21 C.F.R. §1301.74(b). The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. §1301.74(b). *See* 21 U.S.C. §842(a)(5) & (c)(1)(B). The provision requiring the reporting of suspicious orders in the federal CSA has been incorporated into

[214] DrugDistribution Locations – Mainland US, https://batchgeo.com/map/788de3747b01802c0171abfa8a4b5eca (last visited Mar. 14, 2018).

Florida law. Fla. Stat. §499.0121(10) and (15)(b).

340. On December 23, 2016, Cardinal Health agreed to pay the United States $44 million to resolve allegations that it violated the CSA in Maryland, Florida and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA.[215]

341. In the settlement agreement, Cardinal Health admitted, accepted and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

- "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)";
- "maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA's regulations for which a penalty may be imposed under 21 U.S.C. § 842(a)(5)"; and
- "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305."

342. The settlement agreement was announced by the U.S. Attorney for the District of Maryland, Rod J. Rosenstein ("Rosenstein"), and the DEA Special Agent in Charge – Washington Field Division, Karl C. Colder ("Colder").[216]

343. In the press release announcing the settlement agreement, Rosenstein stated:

> "Pharmaceutical suppliers violate the law when they fill unusually large or frequent orders for controlled substances without notifying the DEA.... Abuse

[215] Earlier in 2016, CVS also agreed to pay the United States $8 million to resolve violations of the CSA by its Maryland pharmacies. According to the settlement agreement, CVS admitted that between 2008 and 2012 certain of its Maryland pharmacies dispensed oxycodone, fentanyl, hydrocodone and other pharmaceuticals in violation of the CSA because the drugs were dispensed without ensuring that the prescriptions were issued for legitimate medical purposes.

[216] Press Release, U.S. Attorney's Office for the District of Maryland, Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act (Dec. 23, 2016), https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.

> of pharmaceutical drugs is one of the top federal law enforcement priorities. Cases such as this one, as well as our $8 million settlement with CVS in February 2016, reflect the federal commitment to prevent the diversion of pharmaceutical drugs for illegal purposes."[217]

344. In the press release, Colder clarified that the settlement specifically concerned oxycodone:

> "DEA is responsible for ensuring that all controlled substance transactions take place within DEA's regulatory closed system. All legitimate handlers of controlled substances must maintain strict accounting for all distributions and Cardinal failed to adhere to this policy…. Oxycodone is a very addictive drug and failure to report suspicious orders of oxycodone is a serious matter. The civil penalty levied against Cardinal should send a strong message that all handlers of controlled substances must perform due diligence to ensure the public safety…."[218]

C. AmerisourceBergen

345. AmerisourceBergen is a wholesale distributor of pharmaceuticals, including controlled substances and non-controlled prescription medications. AmerisourceBergen is a significant distributor of opioids in the United States. It handles the distribution of approximately 20% of all pharmaceuticals sold and distributed in the United States through a network of 26 pharmaceutical distribution centers, including one in Orlando, Florida.[219] It ranked 11th on the Fortune 500 list in 2017, with over $146 billion in annual revenue.

346. AmerisourceBergen distribution centers are required to operate in accordance with the statutory provisions of the CSA and the regulations promulgated thereunder, 21 C.F.R. §1300 *et seq.* The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances as that term is defined in the regulation. *See* 21 C.F.R. §1301.74(b). The CSA authorizes the imposition of a civil penalty of up

---

[217] *Id.*
[218] *Id.*
[219] *AmerisourceBergen*, Wikipedia, https://en.wikipedia.org/wiki/AmerisourceBergen (hereinafter "*AmerisourceBergen*") (last visited Mar. 13, 2018); Drug Distribution Locations, *supra* n.245.

to $10,000 for each violation of 21 C.F.R. §1301.74(b). *See* 21 U.S.C. §842(a)(5) & (c)(1)(B). The provision requiring the reporting of suspicious orders in the federal CSA has been incorporated into Florida law. Fla. Stat. §499.0121(10) and (15)(b).

347. In 2012, West Virginia sued AmerisourceBergen and Cardinal Health, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection and antitrust laws, and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal Health, together shipped 423 million pain pills to West Virginia between 2007 and 2012.[220] AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 oxycodone pills during that time period.[221] Moreover, public documents also demonstrate that the average dose of each tablet distributed grew substantially during that time period. The Wholesaler Defendants, including AmerisourceBergen, shipped large quantities of oxycodone and hydrocodone tablets to the state. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit by paying $16 million to the state, with the funds set aside to fund drug treatment programs in order to respond to the opioid addiction crisis.

348. Plaintiff have taken proactive measures in its own health care system to fight against prescription opioid abuse and to use information technologies to combat opioid diversion, including a prescription monitoring program ("PMP").

349. Nonetheless, Plaintiff has been uniquely and significantly damaged by the effects of the Wholesaler Defendants' opioid diversion.

350. The Wholesaler Defendants have the ability and the duty to prevent opioid diversion,

---

[220] Eric Eyre, *Drug firms poured 780M painkillers into WV amid rise of overdoses*, Charleston Gazette-Mail (Dec. 17, 2016), https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_99026dad-8ed5-5075-90fa-adb906a36214.html.
[221] *AmerisourceBergen*, *supra* n.250.

which presented and continues to present a known and foreseeable risk of damage to Plaintiff.

351. The Wholesaler Defendants have supplied massive quantities of prescription opioids in and around the geographic region served by Plaintiff, with the actual or constructive knowledge that the opioids were ultimately being consumed by citizens for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but the Wholesaler Defendants negligently or intentionally failed to do so.

352. On information and belief, the Wholesaler Defendants made little to no effort to visit the pharmacies servicing the patients in the geographic region served by the Plaintiff in order to perform the due diligence inspections necessary to ensure that the controlled substances the Wholesaler Defendants had furnished were not being diverted to illegal uses.

353. On information and belief, the compensation of the Wholesaler Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to pharmacies and other facilities serving Plaintiff's patients and in the geographic region served by Plaintiff, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

354. It was reasonably foreseeable to the Wholesaler Defendants that their conduct in flooding the consumer market in the geographic region served by Plaintiff with highly addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

355. It is reasonably foreseeable to the Wholesaler Defendants that, when unintended users gain access to opioids, tragic, preventable injuries will result, including addiction, overdoses, cardiac problems, and death. It is also reasonably foreseeable that the costs of these injuries would be shouldered by Plaintiff.

356. The Wholesaler Defendants knew or should have known that the opioids being diverted from their supply chains would create access to opioids by unauthorized users, which in turn perpetuates the cycle of addiction, demand, illegal transactions, economic ruin, and human tragedy, and thereby contribute to the opioid-related costs incurred by Plaintiff.

357. The Wholesaler Defendants knew or should have known that a substantial amount of the opioids dispensed to patients of Plaintiff and in the geographic region served by Plaintiff were being dispensed based on invalid or suspicious prescriptions. It is foreseeable that filling suspicious orders for opioids will cause harm to individual pharmacy customers, third parties, and Plaintiff.

358. The Wholesaler Defendants were aware of widespread prescription opioid abuse of persons in the geographic area serviced by Plaintiff, but nevertheless persisted in a pattern of distributing commonly-abused-and-diverted opioids into those geographic areas in such quantities and with such frequency that they knew or should have known these substances were not being prescribed and consumed for legitimate medical purposes.

359. If any of the Wholesaler Defendants had adhered to effective controls to guard against diversion, Plaintiff would have avoided significant damages.

360. The Wholesaler Defendants made substantial profits over the years based on the diversion of opioids affecting Plaintiff. Their participation and cooperation in a common enterprise has foreseeably caused damages to Plaintiff. The Wholesaler Defendants knew full well that Plaintiff would be unjustly forced to bear the costs of these injuries and damages.

361. The Wholesaler Defendants intentional distribution of excessive amounts of prescription opioids to communities in the geographic area services by Plaintiff showed an intentional and/or reckless disregard for Plaintiff and constitutes a continuing economic threat to Plaintiff.

COUNT I – PUBLIC NUISANCE
(Against all Defendants)

362. Plaintiff realleges paragraphs 1 through 361 above as if fully set forth herein.

363. The nuisance is the over-saturation of opioids in the patient population of Plaintiff and in the geographic region served by Plaintiff for non-medical purposes, as well as the adverse social, economic, and human health outcomes associated with widespread, illegal opioid use.

364. Each of the Manufacturing Defendants subverted the public order, decency, and morals of, and caused inconvenience and damage to Plaintiff and in the geographic region served by Plaintiff by, among other things, promoting and marketing the use of opioids for indications not federally approved; circulating false and misleading information concerning their safety and efficacy; and/or downplaying or omitting the risk of addiction arising from their use in violation of the FDUTPA. In so doing, the Manufacturing Defendants acted unreasonably and with actual malice.

365. Each of the Manufacturing Defendants and Wholesaler Defendants subverted the public order, decency, and morals of, and caused inconvenience and damage to, Plaintiff by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances or by failing to report suspicious orders of opioids as required by the federal CSA, 21 C.F.R. §1301.74(b), and by the State of Florida, Fla. Stat. §499.0121(10) and (15)(b). In so doing, the Manufacturing Defendants and Wholesaler Defendants acted unreasonably and with actual malice.

366. Defendants' activities unreasonably interfered and continues to interfere with Plaintiff's economic rights.

367. Defendants' interference with Plaintiff's rights is unreasonable because it:

a. Has harmed and will continue to harm the public health services of and public peace of Plaintiff;

b. Has harmed and will continue to harm the communities and neighborhoods served

by Plaintiff;

c. Is proscribed by statutes and regulations, including the CSA, and the consumer protection statute;

d. Is of a continuing nature and it has produced long-lasting effects; and

e. Defendants have reason to know their conduct has a significant effect upon Plaintiff.

368. The nuisance undermined public health, quality of life, and safety. It has resulted in increased crime and property damage. It has resulted in high rates of addiction, overdoses, dysfunction, sickness, death and despair within families and entire communities.

369. Plaintiff's resources are being unreasonably consumed in efforts to address the prescription drug abuse epidemic, thereby eliminating available resources needed in other health areas.

370. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in failing to identify, halt, and report suspicious opioid transactions.

371. At all times pertinent hereto, Defendants possessed the right and ability to control the nuisance-causing outflow of opioids from pharmacies and other points of sale. Wholesaler Defendants had the power to shut off the supply of illicit opioids to Plaintiff's patients and in the geographic region served by Plaintiff.

372. As a direct and proximate result of the nuisance, Plaintiff has sustained economic harm by spending a substantial amount of money trying to remedy the harms caused by Defendants' nuisance-causing activity, including but not limited to: costs for security, provision of in-patient health care services to users of prescription opioids, staff overtime, mental health treatment and

workers' compensation for its employees, increased emergency and treatment services, and lost productivity and economic opportunity.

373. Plaintiff has also suffered unique harms different from individual opioid user and governmental entities at large, namely, that Plaintiff has been harmed in its proprietary interests.

374. The effects if the nuisance can be abated, and further occurrence of such harm and inconvenience can be prevented. All Defendants share in the responsibility for doing so.

375. Defendants should be required to pay Plaintiff's expenses incurred or will incur in the future to fully abate this nuisance.

COUNT II – NEGLIGENCE
(Against all Defendants)

376. Plaintiff realleges paragraphs 1 through 361 above as if fully set forth herein.

377. Negligence *per se* is established where the defendant violates a statutory duty and where the statute is intended to protect against the result of the violation, the plaintiff is within the class intended to be protected by the statute, and the statutory violation is a proximate cause of the plaintiff's injury. Negligence is established where the defendant owes the plaintiff a duty of care, breaches that duty and the plaintiff sustains an injury or loss proximately caused by the defendant's breach.

378. Defendants owe a non-delegable duty to Plaintiff to conform their behavior to the legal standard of reasonable conduct under the circumstances, in light of the apparent risks.

379. Each of the Manufacturing Defendants owed Plaintiff statutory and common-law duties, including the duty to comply with the FDUTPA's prohibition of "[u]nfair methods of competition, or unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce"; the duty to promote and market opioids truthfully and pursuant to their federally approved indications; and the duty to disclose the true risk of addiction associated

with the use of opioids. Each of the Manufacturing Defendants breached those duties by, among other things, promoting and marketing the use of opioids for indications not federally approved; circulating false and misleading information concerning their safety and efficacy; and/or downplaying or omitting the risk of addiction arising from their use. In so doing, the Manufacturing Defendants acted with actual malice.

380. Each of the Manufacturing Defendants and Wholesaler Defendants owed Plaintiff, acting on its own behalf and on behalf of its patients, the statutory duty to report suspicious sales; the duty to refuse the filling of suspicious orders; the duty to abide by any government agreements entered regarding the same; and the duty to comply with the federal CSA, 21 C.F.R. §1301.74(b), as incorporated by Fla. Stat. §499.0121(10) and (15)(b), which requires the design and operation of a system to detect and disclose suspicious orders of controlled substances. Each of the Manufacturing Defendants and Wholesaler Defendants breached these duties by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances or by failing to report such suspicious orders to the appropriate regulators as required by state and federal law. In so doing, the Manufacturing Defendants and Wholesaler Defendants acted with actual malice.

381. There is no social value to Defendants' challenged and improper behavior as alleged herein.

382. There is immense social value to the interests threatened by Defendants' behavior, namely the health, safety and welfare of Plaintiff and its patients.

383. Defendants' behavior caused a substantial injury and damage to Plaintiff.

384. Defendants' conduct fell below the reasonable standard of care and was negligent. Such negligent acts include:

a. Conspicuously supplying the market in the geographic region served by Plaintiff with

highly addictive prescription opioids;

b. Using unsafe distribution practices;

c. Affirmatively enhancing the risk of harm from prescription opioids by failing to act as a last line of defense against diversion;

d. Failing to properly train, investigate or supervise their employees;

e. Failing to properly review orders for red flags;

f. Failing to report suspicious orders or refusing to fill them;

g. Failing to provide effective controls and procedures to guard against theft and diversion of controlled substances; and

h. Failing to police the integrity of their supply chains.

385. Each Defendant had an ability to control the opioids at a time when it knew or should have known it was passing control of the opioids to an actor further down in the supply chain that was incompetent or acting illegally and should not be entrusted with the opioids.

386. Each Defendant placed prescription opioids into the supply chain knowing both that (a) there was substantial likelihood that many of the sales were for non-medical purposes, and (b) that opioids are an inherently dangerous product when used for non-medical purposes.

387. Defendants were negligent in not acquiring or utilizing special knowledge and special skills relating to the dangerous activity in order to prevent or ameliorate such distinctive and significant dangers.

388. Controlled substances are dangerous commodities. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in the transaction of their business.

389. Defendants were and are also negligent in failing to guard against foreseeable third-

party misconduct, e.g., the foreseeable conduct of corrupt prescribers, corrupt pharmacists and staff, and/or criminals who buy and sell opioids for non-medical purposes.

390. Defendants are in a limited class of registrants authorized to legally distribute controlled substances. This places Defendants in a position of great trust and responsibility vis-à-vis Plaintiff and Plaintiff's patient communities. Defendants owe a special duty to Plaintiff, and that duty cannot be delegated to another party.

391. Plaintiff is without fault, and the injuries to Plaintiff would not have happened in the ordinary course of events if the Defendants used due care commensurate with the dangers involved in the distribution of controlled substances.

392. Plaintiff has suffered both injuries and pecuniary losses proximately caused by the Manufacturing Defendants' and Wholesaler Defendants' breaches.

393. Defendants' breaches of the statutory and common-law duties they each owed to Plaintiff are the proximate cause of this crisis and its resultant harm to Plaintiff.

COUNT III – UNJUST ENRICHMENT
(Against all Defendants)

394. Plaintiff realleges paragraphs 1 through 361 above as if fully set forth herein.

395. Under the doctrine of unjust enrichment, a party who receives a benefit must return the benefit if retention would be inequitable. Unjust enrichment is established where: (a) the plaintiff conferred a benefit upon the defendant; (b) the defendant had knowledge of the benefit; (c) the defendant accepted or retained the benefit conferred; and (d) the circumstances are such that it would be inequitable for the defendant to retain the benefit without paying the plaintiff for its fair value.

396. Plaintiff has expended substantial amounts of money to address, remedy, and/or mitigate the societal harms caused by Defendants' conduct.

397. The expenditures made by Plaintiff alleged herein in providing healthcare services to

people who use opioids, or for services provided by Plaintiff in connection with addressing prescription opioid abuse, have added to Defendants' wealth. Such expenditures conferred on each Manufacturing Defendant a benefit. By making such expenditures, for treatment and emergency services, Plaintiff has assumed the financial burden of paying for externalities that allow Defendants to continue their scheme, which benefit was known to and accepted by each Manufacturing Defendant, which inured to the profits of each Manufacturing Defendant, and for which retention of such benefit is inequitable based on the Manufacturing Defendants' false and misleading marketing and omissions of and failure to state material facts in connection with marketing opioids, as set forth herein. The Manufacturing Defendants have thus been unjustly enriched by deceptive marketing, contributing to the current opioid epidemic in the geographic region served by Plaintiff.

398. The expenditures made by Plaintiff alleged herein in providing healthcare services to people who use opioids, conferred on each Wholesaler Defendant a benefit, including paying for externalities that allow Defendants to continue their scheme without incurring the resultant costs of that scheme, which benefit was known to and accepted by each Wholesaler Defendant, which inured to the profits of each Wholesaler Defendant, and for which retention of such benefit is inequitable based on the Wholesaler Defendants' failure to report suspicious sales as required by law. The Wholesaler Defendants have thus been unjustly enriched by neglecting their duty to distribute drugs only for proper medical purposes, contributing to the current opioid epidemic in the geographic region served by Plaintiff.

399. The unprecedented opioid addiction and overdose epidemic in the geographic region served by Plaintiff has, upon information and belief, cost it millions of dollars in increased expenditure for the provision of health care related services, increased expenditures for overtime, mental health treatment and workers' compensation for its employees, increased emergency and

treatment services, and lost productivity and economic opportunity.

400. The unjust enrichment of the Manufacturing Defendants and Wholesaler Defendants is directly related to the damage, loss and detriment to Plaintiff caused by Defendants' false marketing and failure to report suspicious sales. It would be inequitable under these circumstances for the Manufacturing Defendants and Wholesaler Defendants to retain this benefit without compensating Plaintiff for its value. Plaintiff seeks recovery of the amounts by which the Manufacturing Defendants and Wholesaler Defendants were enriched as a result of their inequitable conduct.

COUNT IV – COMMON LAW FRAUD
(Against all Manufacturing Defendants)

401. Plaintiff realleges paragraphs 1 through 361 above as if fully set forth herein.

402. Manufacturing Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain.

403. Defendant Purdue made and/or disseminated deceptive statements, including but not limited to the following: (a) advertising that opioids improved long-term functioning and were suitable for the treatment of chronic non-cancer pain; (b) promoting the concept of pseudo-addiction; (c) publishing brochures concerning indicators of possible opioid abuse; (d) representing the suitability of opioids for high-risk patients; (e) issuing publications presenting an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDS; (f) concealing the funding of pro-opioid KOL doctors regarding treatment for non-chronic cancer pain; (g) downplaying the risk of opioid addiction; (h) holding CMEs focused on promoting the use of opioids to treat chronic non-cancer pain; (i) promoting misleading scientific studies regarding the safety and efficacy of opioids for long-term treatment of non-cancer pain; (j) misusing and promoting of data to mask the safety and efficacy of opioids for long-term treatment of non-cancer pain, including rates of abuse and addition and the lack of validation for long term efficacy; (k) making misleading

statements in education materials for Florida hospital doctors and staff under the guise of educating them on new pain standards; (l) in person detailing; and (m) withholding from Florida law enforcement the names of prescribers Purdue believe to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials, advertisements, and CMEs.

404. Defendant Endo made and/or disseminated deceptive statements, including but not limited to the following: (a) producing false patient education materials; (b) advertising the ability of opioids to improve the function long-term and the efficacy of opioids long-term for the treatment of chronic non-cancer pain; (c) promoting chronic opioid therapy as safe and effective for long term use by high risk patients; (d) creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse; (e) concealing the true risk of addiction and promoting the misleading concept of pseudo-addiction; (f) promoting an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDS; (g) secretly funding pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain; (h) funding pro-opioid pain organizations responsible for egregious misrepresentations concerning the use of opioids to treat chronic non-cancer pain; (i) downplaying the risks of opioid addition; (j) CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain; (k) misleading scientific studies concluding opioids are safe and effective for the long-term treatment of chronic non-cancer pain and quality of life; (l) funding and promoting pro-opioid KOLs concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudo-addiction; (m) manipulating data regarding safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-

term efficacy; and (n) in-person detailing.

405. Defendants Janssen and J&J made and/or disseminated deceptive statements, including but not limited to the following: (a) producing patient education materials containing deceptive statements regarding the suitability, benefits, and efficacy of opioids; (b) stating that opioids were safe and effective for the long-term treatment of chronic non-cancer pain; (c) stating that opioids improve quality of life, while concealing contrary data; (d) concealing the true risk of addiction; (e) promoting the deceptive concept of pseudo-addiction; (f) promoting opioids for the treatment of conditions which Janssen knew, owing to the scientific studies it conducted, that opioids were not efficacious, and concealing this information; (g) presenting to the public and doctors an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDS; (h) funding pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain; (i) funding pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic, non-cancer pain; (j) using CMEs to promote false statements concerning the use of opioids to treat chronic non-cancer pain; and (k) in-person detailing.

406. Defendant Cephalon made and/or disseminated untrue, false, and deceptive statements including but not limited to the following: (a) minimizing the risk of addiction of opioids; (b) promoting the concept of pseudo-addiction; (c) advocating the use of opioids for chronic non-cancer pain; (d) funding misleading CMEs, KOL doctors, and pain organizations; (e) minimizing the addictiveness of Cephalon's rapid-onset opioids; and (f) promoting the suitability of Cephalon's rapid-onset opioids to general practitioners, neurologists, sports medicine specialists, and workers' compensation programs.

407. These false representations and concealments were reasonably calculated to deceive

prescribing physicians in the geographic region served by Plaintiff, were made with intent to deceive, and did in fact deceive physicians who prescribed opioids for chronic pain.

408. But for these representations and concealments of material fact, Plaintiff would not have incurred substantial costs and economic loss.

409. Plaintiff has suffered damages as a direct and proximate cause of Defendants' fraudulent conduct.

COUNT V – VIOLATION OF THE RICO ACT, 18 U.S.C. § 1962(C)-(D)
(Against all Defendants)

410. Plaintiff realleges paragraphs 1 through 361 above as if fully set forth herein.

411. At all relevant times, Defendants have been "persons" under 18 U.S.C. §1961(3) because they are capable of holding, and do hold, a "legal or beneficial interest in property."

412. The Racketeer Influenced and Corrupt Organizations Act ("RICO") makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. §1962(c).

413. RICO, among other provisions, makes it unlawful for "any person to conspire to violate" the provisions of 18 U.S.C. §1962(c). 18 U.S.C. §1962(d).

414. As alleged herein, at all relevant times, Defendants moved aggressively to capture a large portion of the opioid sales market. In so doing, the Manufacturing Defendants launched an aggressive nationwide campaign over-emphasizing the under-treatment of pain and deceptively marketing opioids as being: (i) rarely, if ever, addictive; (ii) safe and effective for the treatment of chronic long-term pain; (iii) abuse resistant or deterrent; or (iv) safe and effective for other types of pain for which the drugs were not approved. All Defendants knowingly failed to report suspicious orders as required by state and federal law, thereby inundating the market with opioids. In particular,

Defendants, along with other entities and individuals, were employed by or associated with, and conducted or participated in the affairs of, one or several RICO enterprises (the "Opioid Fraud Enterprise"), whose purpose was to deceive opioid prescribers, the public, and regulators into believing that opioids were safe and effective for the treatment of long-term chronic pain and presented minimal risk of addiction and/or that Defendants were in compliance with their state and federal reporting obligations. In doing so, Defendants sought to maximize revenues from the design, manufacture, sale and distribution of opioids which, in fact, were highly addictive and often ineffective and dangerous when used for long term, chronic and other types of pain. As a direct and proximate result of their fraudulent scheme and common course of conduct, Defendants were able to extract billions of dollars of revenue. As explained in detail below, Defendants' years-long misconduct violated 18 U.S.C. § 1962(c) and (d).

a) The Opioid Fraud Enterprise

415. At all relevant times, Defendants, along with other individuals and entities, including unknown third parties involved in the marketing and sale of opioids, operated an "enterprise" within the meaning of 18 U.S.C. § 1961(4), because they are a group of individuals associated in fact, even though they are not a collective legal entity. The Opioid Fraud Enterprise: (a) had an existence separate and distinct from each of its component entities; (b) was separate and distinct from the pattern of racketeering in which Defendants engaged; and (c) was an ongoing organization consisting of legal entities, including, but not limited to, the Manufacturing Defendants, the Wholesaler Defendants, pharmacies, employees and agents of the FSMB, APF, AAPM, APS and APA, as well as other entities and individuals, including physicians.

416. Within the Opioid Fraud Enterprise, there was a common communication network by which members exchanged information on a regular basis through the use of wires and mail. The

Opioid Fraud Enterprise used this common communication network for the purpose of deceptively marketing, selling and distributing opioids to the general public. When their products, sales, distributions and failure to report suspicious sales were contested by other parties, the enterprise members took action to hide the scheme to continue its existence.

417. The participants in the Opioid Fraud Enterprise were systematically linked to each other through corporate ties, contractual relationships, financial ties and the continuing coordination of activities. Through the enterprise, Defendants functioned as a continuing unit with the purpose of furthering the illegal scheme and their common purposes of increasing their revenues and market share, and minimizing losses. Each member of the Opioid Fraud Enterprise shared in the bounty generated by the enterprise by sharing the benefit derived from increased sales of opioids and other revenue generated by the scheme to defraud prescribers and consumers and fail to report suspicious sales in the geographic region served by Plaintiff.

418. The Opioid Fraud Enterprise engaged in and continues to engage in the deceptive marketing of opioids as non-addictive, as safe and effective for chronic long-term pain and for uses which have not been FDA-approved, and the failure to report suspicious sales. The Opioid Fraud Enterprise has engaged in such activity for the purpose of maximizing the sale and profits of opioids. To fulfill this purpose, the enterprise has advocated for and caused the over-prescription and over-distribution of opioids by marketing, promoting, advertising and selling opioids throughout the country and across state boundaries and by failing to report suspicious sales. Their receipt of monies from such activities consequentially affected interstate and foreign commerce. The enterprise's past and ongoing practices thus constitute a pattern of racketeering activity under 18 U.S.C. § 1961(5).

419. The Opioid Fraud Enterprise functioned by marketing, selling and distributing opioids to states, counties, other municipalities, doctors, healthcare organizations, pharmacies and

the consuming public, while failing to report suspicious sales. However, Defendants as co-conspirators, through their illegal enterprise, engaged in a pattern of racketeering activity, which involves a fraudulent scheme to increase revenue for Defendants and the other entities and individuals associated-in-fact with the enterprise's activities through the deceptive marketing and sale of opioids and the failure to report suspicious sales.

420. Defendants participated in the operation and management of the Opioid Fraud Enterprise by directing its affairs, as described herein. While Defendants participated in, and are members of the enterprise, they have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements and financial statements.

421. Each of the members of the Opioid Fraud Enterprise furthered the ends of the enterprise, through the acts and omissions pleaded above and herein.

422. Each of the Manufacturing Defendants relentlessly promoted opioids as having little to no risk of addiction, as being safe and effective for the treatment of long-term chronic pain and/or other uses for which the drugs were not approved. The Manufacturing Defendants' success in maximizing sales was due to the tight collaboration among the Manufacturing Defendants through and in collaboration with the pain foundations – a formidable partnership that marketed to hundreds of thousands of prescribers across the country, including prescribers in the geographic region served by Plaintiff. The relationship was strengthened, in part, by individuals, including physicians, that held different leadership roles at different times across the various entities participating in the enterprise over the years.

423. On numerous occasions, the Manufacturing Defendants funded the pain foundations' marketing efforts. The Manufacturing Defendants specifically chose to partner with the pain

foundations and individual physicians to publish and otherwise disseminate misleading pro-opioid material, knowing the public and prescribers would be more receptive to statements made by what they perceived to be scholarly, neutral, third party sources.

424. Further, all Defendants knowingly failed to design and operate a system to disclose suspicious orders of controlled substances and failed to notify the appropriate DEA field division offices in their areas of suspicious orders, including "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

425. The members of the Opioid Fraud Enterprise worked together to further the enterprise by and among the following manner and means:

a. jointly planning to deceptively market and manufacture opioids that were purportedly non-addictive, safe and effective for the treatment of chronic, long-term pain;

b. concealing the addictive qualities of the opioids from prescribers and the public;

c. misleading the public about the addictive quality and safety and efficacy of opioids;

d. otherwise misrepresenting or concealing the highly dangerous nature of opioids from prescribers and the public;

e. illegally marketing, selling, and/or distributing opioids;

f. collecting revenues and profits from the sale of such products for uses for which they are unapproved, unsafe, or ineffective; and/or

g. failing to report suspicious sales as required by the CSA.

426. To achieve their common goals, Defendants hid from the general public the full extent of the unsafe and ineffective nature of opioids for chronic pain as described herein. Defendants suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the addictive, unsafe and often ineffective nature of opioids.

427. The foregoing allegations support that Defendants were part of an association of entities that shared a common purpose, had relationships across the various members of the enterprise and collaborated to further the goals of the enterprise for a continuous period of time. Manufacturing Defendants knowingly and intentionally engaged in deceptive marketing practices, and incentivized pain foundations, marketing firms and physicians to do so as well. Defendants knowingly and intentionally failed to report suspicious orders as required by state and federal law and inundated the market with opioids.

b) Mail and Wire Fraud

428. To carry out and attempt to carry out the scheme to defraud, Defendants, each of whom is a person associated in fact with the enterprise, did knowingly conduct and participate, directly and indirectly, in the conduct of the affairs of the enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c), and which employed the use of the mail and wire facilities, in violation of 18 U.S.C. §§ 1341 (mail fraud) and 1343 (wire fraud).

429. Specifically, Defendants have committed, conspired to commit and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§ 1341 and 1343), within the past four years. The multiple acts of racketeering activity which Defendants committed, or aided and abetted in the commission of, were related to each other and also posed a threat of continued racketeering activity. They therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by Defendants' regular use of the facilities, services, distribution channels and employees of the enterprise. Defendants participated in the scheme to defraud by using the mail, telephone and Internet to transmit mailings and wires in interstate or foreign commerce.

430. In devising and executing the illegal scheme, Defendants devised and knowingly carried out a material scheme and/or artifice to defraud regulators, prescribers and the public to obtain money from Plaintiff by means of materially false or fraudulent pretenses, representations, promises or omissions of material facts. For the purpose of executing the illegal scheme, Defendants committed these racketeering acts intentionally and knowingly with the specific intent to advance the illegal scheme.

431. Defendants' predicate acts of racketeering, 18 U.S.C. § 1961(1), include, but are not limited to:

a. Mail Fraud: Defendants violated 18 U.S.C. § 1341 by sending and receiving, and by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to deceptively market, sell and distribute the opioids by means of false pretenses, misrepresentations, promises and omissions; and

b. Wire Fraud: Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, and by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to defraud and obtain money on false pretenses, misrepresentations, promises and omissions.

432. Defendants' use of the mails and wires include, but are not limited to, the transmission, delivery and shipment of deceptive marketing materials; the filling of suspicious orders; and the misleading of regulators and the public as to Defendants' compliance with their state and federal reporting obligations. These materials would not have been delivered, orders would not have been filled, and regulators would have not been misled but for Defendants' illegal scheme, including, but not limited to:

a. the FSMB's publication of opioid prescribing guidelines entitled "Responsible Opioid Prescribing: A Physician's Guide," by Fishman;

b. the FSMB's publication of "Responsible Opioid Prescribing: A Clinician's Guide (Second Edition, Revised and Expanded)," by Fishman;

c. the APF's publication of Exit Wounds;

d. the AAPM's "consensus statement" and educational programs featuring Fine;

e. the APA's publication and dissemination of "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse";

f. false or misleading communications to the public and to regulators;

g. failing to report suspicious orders as required by state and federal law;

h. sales and marketing materials, including slide decks, presentation materials, purported guidelines, advertising, web sites, product packaging, brochures, labeling and other writings which misrepresented, falsely promoted and concealed the true nature of opioids;

i. documents intended to facilitate the manufacture and sale of opioids, including bills of lading, invoices, shipping records, reports and correspondence;

j. documents to process and receive payment for opioids, including invoices and receipts;

k. payments to the foundations and physicians that deceptively marketed the Manufacturing Defendants' opioids;

l. deposits of proceeds; and

m. other documents and things, including electronic communications.

433. Defendants also used the Internet and other electronic facilities to carry out the scheme and conceal the ongoing fraudulent activities. For example, the Manufacturing Defendants

made misrepresentations about opioids on their websites, YouTube and through online ads, all of which were intended to mislead prescribers and the public about the safety, efficacy and non-addictiveness of opioids.

434. Defendants also communicated by U.S. mail, by interstate facsimile and by interstate electronic mail with various affiliates, regional offices, divisions, distributors, regulators and other third-party entities in furtherance of the scheme. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive prescribers, consumers and regulators, oversupply the market, and fail to report suspicious sales.

435. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities are concealed from Plaintiff and cannot be alleged without access to Defendants' books and records. However, Plaintiff has described the types of predicate acts of mail and/or wire fraud that occurred. The secretive nature of the enterprise's activities made the unlawful tactics discussed herein even more deceptive and harmful.

436. The foregoing allegations support that: the Manufacturing Defendants engaged in a pattern of racketeering activity by repeatedly engaging in wire and mail fraud to deceptively market their products through the use of both print and electronic outlets; and all Defendants engaged in a pattern of racketeering activity by repeatedly engaging in wire and mail fraud to deceive regulators and oversupply the market while failing to report suspicious sales.

c) Conspiracy Allegations

437. Defendants have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. § 1962(d), the Defendants conspired to violate 18 U.S.C. § 1962(c), as described herein.

438. Defendants conspired to incentivize and encourage various other persons, firms and

corporations, including third-party entities and individuals not named as Defendants in this complaint, to carry out offenses and other acts in furtherance of the conspiracy. Defendants conspired to increase or maintain revenues, increase market share and/or minimize losses for the Defendants and their other collaborators throughout the illegal scheme and common course of conduct. In order to achieve this goal, the Defendants engaged in the aforementioned predicate acts on numerous occasions. Defendants, with knowledge and intent, agreed to the overall objectives of the conspiracy and participated in the common course of conduct to commit acts of fraud and indecency in defectively marketing and/or selling opioids through the use of mail and wire fraud.

439. Indeed, for the conspiracy to succeed, each of the Defendants had to agree to deceptively market, sell and/or distribute opioids while failing to report suspicious sales. The unanimity of the Manufacturing Defendants' marketing tactics and all Defendants' failure to report suspicious sales gave credence to their misleading statements and omissions to prescribers, consumers and regulators and directly caused opioids to inundate the market in the geographic region served by Plaintiff.

440. Defendants knew and intended that government regulators, prescribers, consumers, and others, including the geographic region served by Plaintiff, would rely on the collective material misrepresentations and omissions made by them and the other enterprise members about opioids and suspicious sales. Defendants knew and recklessly disregarded the cost that would be suffered by the public, including Plaintiff.

441. The Manufacturing Defendants knew that by partnering with the pain foundations and individual physicians who carried a more neutral public image, they would be able to attribute more scientific credibility to their products, thereby increasing their sales and profits.

442. Defendants also knew that by filling and failing to report suspicious sales, they would

significantly increase their sales and profits.

443. The foregoing illustrates Defendants' liability under 18 U.S.C. § 1962(d), by engaging in their pattern of racketeering and conspiring to achieve their common goal of maximizing opioid sales.

d) Effect on Plaintiff

444. As described herein, Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from consumers, based on their misrepresentations and omissions. The predicate acts also had the same or similar results, participants, victims and methods of commission. The predicate acts were related and not isolated events. The predicate acts all had the purpose of generating significant revenue and profits for Defendants, at the expense of Plaintiff. The predicate acts were committed or caused to be committed by Defendants through their participation in the enterprise and in furtherance of their fraudulent scheme, and were interrelated in that they involved obtaining Plaintiff's funds.

445. As more fully alleged herein, Plaintiff, together with hundreds of other hospitals, relied upon representations and omissions that were made or caused by Defendants.

446. Plaintiff's injuries were proximately caused by Defendants' racketeering activity. But for Defendants' misstatements and omissions and the scheme employed by the Opioid Fraud Enterprise, Plaintiff would not be bearing the costs of its current opioid epidemic.

447. By reason of, and as a result of the conduct of each of the Defendants, and in particular, their pattern of racketeering activity, Plaintiff has been injured in its business and property in multiple ways, including, but not limited to, suffering increased security expenditures, increased expenditures for the provision of in-patient health care services to users of prescription opioids, staff

overtime, mental health treatment and workers' compensation for its employees, increased emergency and treatment services, lost productivity and economic opportunity.

448. Defendants' violations of 18 U.S.C. §1962(c) and (d) have directly and proximately caused injuries and damages to Plaintiff, and Plaintiff is entitled to bring this action for three times its actual damages, as well as injunctive/equitable relief, costs and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that the Court grant the following relief:

A. Enjoin the Manufacturing Defendants from violating Fla. Stat. § 501.021 *et seq.*, by making any further false or misleading statements or omissions related to opioids;

B. Enjoin the Manufacturing Defendants and the Wholesaler Defendants from failing to report suspicious orders as required by the federal CSA, as incorporated by Fla. Stat. § 499.0121(10) and 15(b);

C. Order Defendants to pay costs, losses, and damages for injuries sustained by Plaintiff as a proximate result of the Manufacturing Defendants' and the Wholesaler Defendants' unlawful conduct as set forth herein, including restitution, disgorgement of unjust enrichment, actual damages, exemplary damages, punitive damages, and attorneys' fees and costs; and

D. Grant any such further relief as the Court deems appropriate.

JURY DEMAND

Plaintiff demands a trial by jury.

Dated this 15th day of July, 2021.

Respectfully Submitted,

Timothy M. Hartley, Esquire
FBN: 979066
Hartley Law Offices, PLC
12 Southeast Seventh Street
Suite 610
Fort Lauderdale, Florida 33301
Telephone: (954) 357-9973
Facsimile: (954) 357-2275
Email: hartley@hartleylaw.net

William E. Robertson, Jr., Esq.
FBN: 436607
The Robertson Law Firm, P.A.
1990 9th Street
Suite 100
Sarasota, Florida 34236
Telephone: (941) 364-2455
Facsimile: (941) 365-5828
Email: bill@robertson.law

Attorneys for Plaintiff